

**WEIGHT MAINTENANCE FOLLOWING THE COMPLETION OF A WEIGHT LOSS  
TRIAL: EXPLORING RACIAL DIFFERENCES**

by

**Melanie Warziski Turk**

BSN, Duquesne University, 1995

MSN, University of Pittsburgh, 2008

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SCHOOL OF NURSING

This dissertation was presented

by

Melanie Warziski Turk

It was defended on

July 10, 2008

and approved by

Linda J. Ewing, PhD, RN, Assistant Professor, School of Medicine

Marilyn Hravnak, PhD, CRNP, FAAN, Associate Professor, School of Nursing

Susan M. Sereika, PhD, Associate Professor, School of Nursing

Kyeongra Yang, PhD, MPH, RN, Assistant Professor, School of Nursing

Dissertation Advisor: Lora E. Burke, PhD, MPH, FAAN, Professor, School of Nursing

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# **WEIGHT MAINTENANCE FOLLOWING THE COMPLETION OF A WEIGHT LOSS TRIAL: EXPLORING RACIAL DIFFERENCES**

Melanie Warziski Turk, PhD

University of Pittsburgh, 2008

Overweight and obesity are widespread, global health problems due in part to the relapse and weight gain that often follows weight loss treatment. Moreover, racial minorities are disproportionately affected by this chronic disorder. Empirical evidence is needed to better address the problem of poor weight maintenance after loss.

This ancillary, prospective study examined weight maintenance 18 months after a behavioral weight loss trial and explored possible differences between black and white participants in percent weight change and successful weight maintenance. The relationships of psychosocial variables— experiences following a low-fat diet, barriers to healthy eating, self-efficacy for resisting eating and for exercising, social support, and stress— with weight maintenance were investigated as well as whether race moderated these relationships. Additionally, the study examined the behavioral strategies used for weight maintenance and explored dietary intake and physical activity as potential mediators of the relationship between psychosocial variables and weight maintenance.

Hierarchical linear and logistic regression models were used to examine the effect of race, as well as the effect of psychosocial variables, on percent weight change and successful weight maintenance (defined as  $\leq 5\%$  weight regain), after controlling for age, gender, education, income, and marital status. Descriptive statistics and group comparative statistics (*t*-tests or Mann Whitney U tests) were used to examine behavioral strategies utilized for weight

maintenance. Path analysis investigated possible mediation effects of lifestyle variables on percent weight change.

Fifty-seven percent of the 107 participants (58% of the 81 white participants and 54% of the 26 black participants) were successful weight maintainers. No difference was found in weight maintenance between racial groups; black and white individuals gained a similar amount of weight ( $M = 5.0\%$ ,  $SD = 6.6\%$  and  $M = 4.4\%$ ,  $SD = 5.6\%$ , respectively). An increase in barriers to healthy eating and the impact of a stressful life event on eating affected the percent weight gained and unsuccessful weight maintenance,  $ps < .04$ . Most behavioral strategies for weight maintenance were used less than half the time. Dietary intake and physical activity did not mediate the relationship between the examined psychosocial variables and weight maintenance.

A difference in weight maintenance between black and white individuals was not supported by this study. Future research should further explore the weight control barriers that individuals experience and the impact of stress on weight maintenance.

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## **PREFACE**

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Thank you to my incredibly supportive family and friends. To Mom, Dad, Amy and Brian, thank you for your constant encouragement, understanding, and love. Thank you for enduring the sacrifices necessary for me to achieve this goal. To my husband, Ed, I give my endless gratitude and love for his continuous support and unfailing belief in my abilities. Without your suggestion, I would not have achieved this accomplishment. To all of my friends, thank you for your genuine support and encouragement during this long journey.

## **1.0 PROPOSAL**

### **1.1 SPECIFIC AIMS**

Obesity is a pervasive, chronic health problem associated with an exceptionally high rate of recidivism (Mokdad et al., 2003; Wadden, Brownell, & Foster, 2002). Currently, 66.3% of the U.S. population is either overweight (Body Mass Index or BMI 25-29.9 kg/m<sup>2</sup>) or obese (BMI  $\geq$  30 kg/m<sup>2</sup>) (Centers for Disease Control and Prevention, 2007), with significant increases in the overweight prevalence among children and adolescents and obesity prevalence in men between 1999 and 2004 (Ogden, Carroll, Curtin, McDowell, Tabak, & Flegal, 2006). Moreover, racial minorities are affected in greater proportions by the problem of overweight and obesity. The overall prevalence of obesity for non-Hispanic Blacks was 45% in 2003-2004, compared to 36.8% for Mexican Americans, and 30.6% for non-Hispanic Whites (Ogden et al., 2006). Moreover, women are at higher risk (U.S. Preventive Services Task Force, 2003), especially minority women. Nearly 54% of African American women and 42.3% of Mexican American women are obese compared to 30.2% of non-Hispanic white women (Ogden et al., 2006). A major problem in obesity research is the paucity of investigations focused on racial groups who are at the most risk for obesity and its complications (Kumanyika, 1993; Kumanyika et al., 2005). While obesity researchers have succeeded over the last 20 years in enhancing the amount of weight loss achieved initially (Jeffery et al., 2000), the principal challenge in the treatment of

overweight and obesity is determining strategies that can improve long-term weight maintenance after a loss. However, prior to developing interventions to improve maintenance, we first need to understand what factors may influence successful maintenance and particularly if there are differences across racial minorities. Therefore, the purpose of this descriptive, ancillary study is to determine if there are differences between black and white persons in long-term weight maintenance after an 18-month randomized clinical weight-loss trial.

In the randomized clinical 2 x 2 design of the parent study, Paving the Road to Everlasting Food and Exercise Routines (PREFER) participants were randomly assigned to receive either their treatment preference or not. Participants indicated their preferred treatment, choosing between a low-fat, reduced-calorie lacto-ovo-vegetarian (LOV) diet or a standard low-fat, reduced-calorie diet, as part of a behavioral intervention comparing the effects of these two eating plans and treatment preference on weight loss, adherence to diet and exercise, and lipid changes. Individuals randomized to treatment Preference- Yes were assigned to their preferred diet plan. Those randomized to treatment Preference- No were then randomized to receive either the standard or LOV diet, without regard to their preference. The behavioral intervention, based on social cognitive theory, focused on strategies for changing eating and exercise habits and included 6 months of weekly meetings, 3 months of bi-weekly meetings, and 3 months of monthly meetings, for a total of 12 months (33 sessions) of active treatment; a 6-month period followed with no intervention sessions.

In this study, weight maintenance in minority persons who identify themselves as Black or African American, based on the PREFER population demographics, will be described and explored in comparison to non-minorities, those persons who identify themselves as White. For the purposes of this proposal, Black shall refer to individuals who have self-identified as Black



or African American except in the literature review where the original authors' terms for racial group are followed. This study will adopt the criteria of successful long-term weight maintenance common in the weight maintenance literature,  $\leq 10\%$  weight regain over a minimum of one year (Vogels & Westerterp-Plantenga, 2007; Wing & Hill, 2001). A weight loss of 5-10% is recommended to reduce obesity-related health risk factors (Klein et al., 2004; National Heart Lung and Blood Institute Obesity Education Initiative Expert Panel on the Identification Evaluation and Treatment of Overweight and Obesity, 1998; World Health Organization, 1997).

*The primary aims are to:*

1. Investigate if there are differences between black and white persons in the percentage of weight change, as well as successful weight maintenance defined as  $\leq 10\%$  weight regain, at 18 months post-completion of the PREFER study.
2. Describe the behavioral strategies utilized by black and white persons for weight maintenance after the PREFER study.
3. Examine the influence of possible predictors (self-efficacy, experiences in following a low-fat diet, barriers to healthy eating) on the percentage of weight change and successful weight maintenance as well as whether race moderates the relationship between identified predictors and weight maintenance.

*The secondary aims are to:*

1. Describe the impact of social support on weight maintenance for black and white persons.
2. Describe the impact of stress on weight maintenance for black and white persons.
3. Explore the roles of dietary intake and physical activity as potential mediators of the relationship between weight maintenance and 1) experiences in following a low-fat diet, 2)

barriers to healthy eating, 3) self-efficacy, 4) social support, and 5) stress.

## **1.2 BACKGROUND AND SIGNIFICANCE**

The literature review will use terms for racial groups as used by the original authors with the recognition that individual members of minority populations may identify themselves differently.

### **1.2.1 Theoretical model**

The framework for this study is based on Social Cognitive Theory (SCT). SCT originally developed as social learning theory (Bandura, 1977) but later became social cognitive theory to incorporate the important role of cognition in individuals' behaviors (Bandura, 1986). According to the social cognitive perspective, individuals neither are compelled by inner drives nor are they inevitably shaped and regulated by external stimuli. Instead, human action is described by triadic reciprocity, or reciprocal determinism, where, person, environment, and behavior all function as interacting influences and determinants of each other. SCT is a theoretical framework for examining human motivation, thinking, and action from a standpoint that emphasizes the reciprocal interaction of these factors (Bandura, 1986). Social cognitive theory emphasizes that the individual is a proactive and interactive entity rather than a reactive entity being molded by environmental influences (Bandura, 2001).

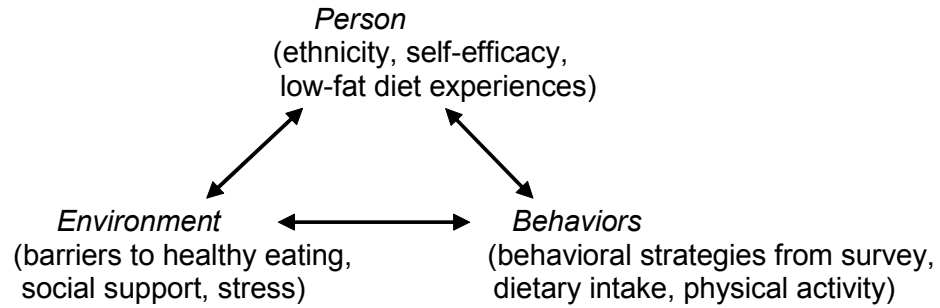
Because weight maintenance is a complex multi-factorial process, social cognitive theory, with the concept of reciprocal determinism, was determined to be an appropriate foundation for this research. Percentage of weight loss maintained will be affected by these

realms of influence e.g., the environmental factors of barriers to healthy eating, social support, and stress together with personal factors of race, efficacy beliefs and experiences associated with eating a low-fat diet, as well as dietary intake, physical activity, and behavioral weight maintenance strategies utilized by participants. To overcome the obstacles individuals are faced with in life, they need social supports, or resources, to supply importance and value to what they do. When social connections are insubstantial or absent, susceptibility to harmful influences is increased (Bandura, 1989). This theoretical concept suggests that persons with insufficient social support for a behavior or goal may be vulnerable to negative influences that cause weight regain.

Self-efficacy is a component of SCT and describes a person's judgments regarding the ability to execute actions needed to perform selected behaviors (Bandura, 1997). Self-efficacy highlights the vital role an individual's estimations of his/her capabilities play in behavior change, to the extent that perceived self-efficacy is a major determinant of performance independent of actual underlying skill (Bandura, 1986). Moreover, individuals are more likely to continue their efforts toward successful achievement if their perceived self-efficacy is higher (Bandura, 1982). Yet, inconsistencies have been reported regarding self-efficacy and weight management. While some have noted higher self-efficacy is associated with more successful weight loss and maintenance (Dennis & Goldberg, 1996; Richman, Loughnan, Droulers, Steinbeck, & Caterson, 2001), others have found that increased self-efficacy levels prior to treatment were associated with less weight loss in African American women (Martin, Dutton, & Brantley, 2003). These findings might indicate that a high baseline self-efficacy is a sign of overconfidence or lack of experience with the challenges of weight loss (Martin et al., 2003). Although various studies have investigated the relationship between self-efficacy and weight loss, the role of self-efficacy in weight maintenance is not well described. Linde and colleagues

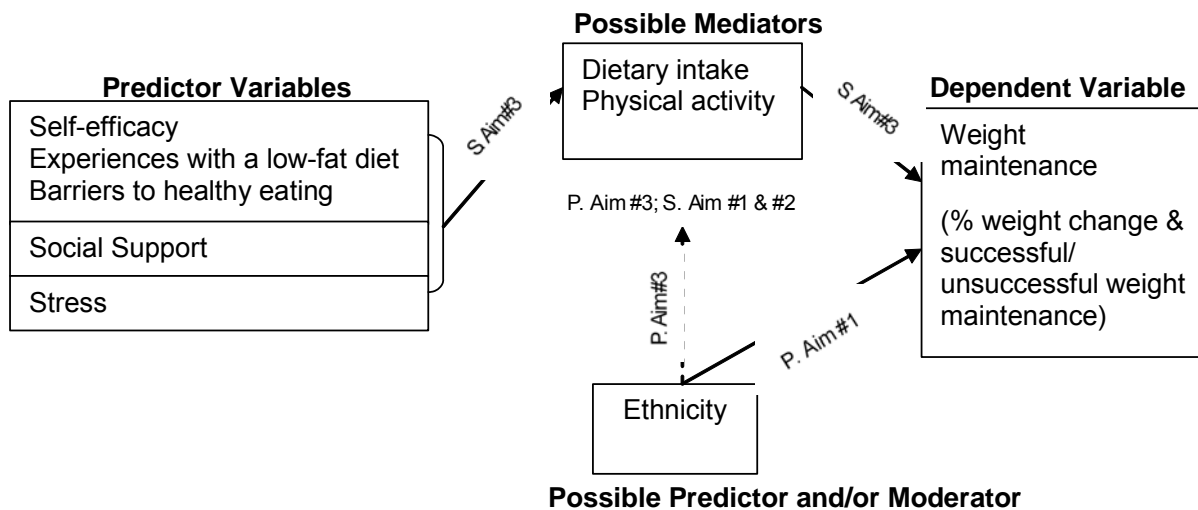
reported that eating self-efficacy was predictive of weight-loss behaviors like counting calories and eating less fat, but self-efficacy was not associated with weight change during the follow-up period (2006). Conversely, other researchers have found that self-efficacy is associated with successful weight management in individuals who had been overweight in the past (Kitsantas, 2000). These findings suggest that self-efficacy during weight maintenance and potential racial differences with self-efficacy and weight control need to be explored.

The purpose of the dissertation study is to describe and explore weight maintenance for black and white persons using the theoretical foundation of SCT and reciprocal determinism, a model that explains the shared interaction between the three causal factors of person, environment, and behavior, and the mutual impact each has on the others in describing human behavior (Bandura, 1986). Figure 1.1 represents the theoretical model with variables of interest for the dissertation study based on the concept of reciprocal determinism from SCT. The three elements are represented as: 1) Person— race, self-efficacy for eating and exercise, experiences associated with following a low-fat diet; 2) Environment— barriers to healthy eating, social support, stress; and 3) Behaviors— behavioral strategies used to support maintenance of lost weight, dietary intake and physical activity.

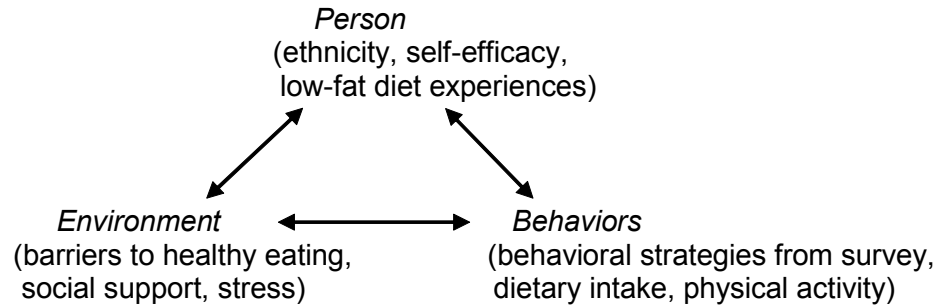


**Figure 1.1: Theoretical model based upon reciprocal determinism adapted for this study**

However, the interactivity of these elements will not be directly tested in this study. Thus, the conceptual framework for examining the specific aims is depicted in Figure 1.2. The dissertation study will examine self-efficacy, experiences associated with following a low-fat diet, barriers to healthy eating, social support, and stress, as well as possible mediating variables (dietary intake and physical activity) and their relationship with weight maintenance in black and white persons.

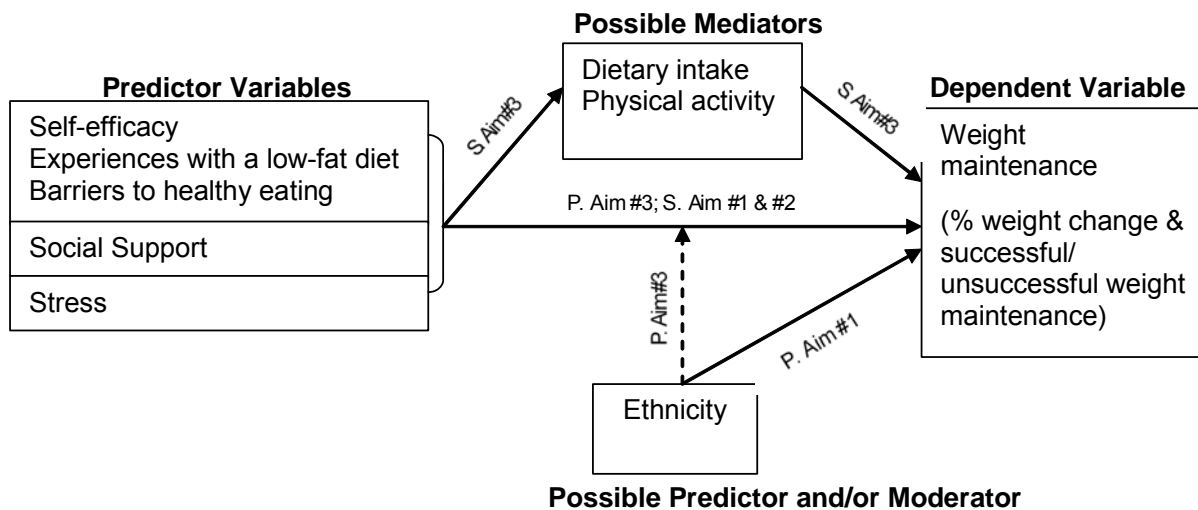


**Figure 1.2: Conceptual framework**



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**Figure 1.2: Conceptual framework**

restaurants per square mile in communities with only 20% Blacks. Comparing neighborhoods of similar size, black communities had easy access to six more fast-food restaurants than mostly white neighborhoods (Block, Scribner, & DeSalvo, 2004), and 4 times as many supermarkets, with a wider variety of healthier food options, are located in white neighborhoods compared to black neighborhoods (Morland, Wing, Diez Roux, & Poole, 2002). This suggests that minority populations may not have the same opportunities in their living environment as Whites to make healthier food choices.

Psychological and physiological influences on weight maintenance have been noted as well. Psychological components contributing to weight regain include boredom (Smith, Wing, & Burke, 2000; Wing & Jeffery, 2003), unrealistic weight-loss goals (Cooper & Fairburn, 2001; Dalle Grave et al., 2005; Giusti, Suter, Heraief, Gaillard, & Burckhardt, 2003), and inadequate coping or problem-solving abilities (Drapkin, Wing, & Shiffman, 1995; Kayman, Bruvold, & Stem, 1990). A decrease in eating restraint, or eating control, and increase in disinhibition, or loss of eating control, have also been noted to play a role in weight regain after loss (McGuire, Wing, Klem, Lang, & Hill, 1999; Niemeier, Phelan, Fava, & Wing, 2007; Wing & Hill, 2001). A physiological contributor to regain is decreased metabolic rate, both in resting energy expenditure (REE) (Foster, Wadden, Swain, Anderson, & Vogt, 1999) and activity energy expenditure (AEE) (Weinsier, Hunter, Schutz, Zuckerman, & Darnell, 2002). In fact, Foster and colleagues found that black participants had significantly larger decreases in REE after calorie restriction and weight reduction than did white participants (1999). Weinsier et al. found that after weight loss, AEE and aerobic capacity significantly increased in white women, but significantly decreased in black women (2002). Others have noted significantly lower REE in African Americans compared to Whites (Chitwood, Brown, Lundy, & Dupper, 1996; Jakicic &

Wing, 1998). These findings suggest that further investigation of racial differences is warranted. While specific measurements of metabolic rate will not be performed, the dissertation study will examine, at completion of the PREFER study and 18 months post-completion, an estimation of weekly energy expenditure from leisure-time activities and in light (5 kcal/min), moderate (7.5 kcal/min), and vigorous (10 kcal/min) intensity activity using the Paffenbarger Activity Questionnaire (Paffenbarger, Wing, & Hyde, 1978).

### **1.3.2 Racial minorities**

Minority populations are affected by some medical conditions linked to overweight and obesity at a higher rate than their white counterparts. Obesity-related diseases like diabetes, hypertension, and cardiovascular disease are more prevalent in minority persons (Cossrow & Falkner, 2004; Smith et al., 2005; Sundquist, Winkleby, & Pudaric, 2001). In 2005 in the U.S., the prevalence of type 2 diabetes among adults was greater for African Americans and Hispanics than for Whites (Centers for Disease Control and Prevention, 2005). African Americans are more likely to be obese than individuals of European ancestry (Jeffery et al., 2000). Although the risk of weight gain is common to all Americans and the greatest increase in weight occurs between ages 25 and 44, the rate of change is more acute in black women. An examination of weight change over a 20-year period found that white women aged 25 to 35 gained 7.7 kg while black women the same age gained almost 11 kg over 20 years (Sheehan, DuBrava, DeChello, & Fang, 2003). Weight reduction and maintenance are key factors in decreasing the disproportionate burden of disease in racial minority groups (Kumanyika, 2002).

Empirical findings suggest that there are differences related to weight management between black and white persons. Nies and colleagues assessed health-promoting activities in 86



obese and non-obese women and found that there were essentially no major differences between African American and European Americans in health-promoting behavior except in the area of nutrition. African American women scored lower on the nutrition subscale of the Health-Promoting Lifestyle Profile (Nies, Buffington, Cowan, & Hepworth, 1998). African American women use more commercial diet tools and participate in weight-loss behaviors for less time than white women who weigh significantly less (Tyler, Allan, & Alcozer, 1997). A reduced amount of time spent participating in weight-loss strategies may foreshadow a problem for successful weight maintenance, as necessary behaviors must be adopted for the long-term.

Researchers have noted that black women are concerned about excess weight but are not as successful in their weight management efforts as white women (Kumanyika, Obarzanek, Stevens, Hebert, & Whelton, 1991). Inconsistencies are reported related to weight loss and minorities, however. The Diabetes Prevention Trial (DPP) enrolled over a 45% representation of minority participants (19.9% African American, 15.7% Hispanic, 5.3% American Indian, 4.4% Asian) and saw a 58% reduction in diabetes with a mean weight loss of 5.6 kg. In the DPP, the lifestyle intervention was designed so that participants would achieve and maintain a weight loss of at least seven percent of baseline body weight by following a reduced-calorie, reduced-fat diet and participating in moderate intensity physical activity, like brisk walking, for a minimum of 150 minutes each week. This intervention was equally effective across all racial/ethnic groups over an average of 2.8 years (Knowler et al., 2002). Some have found that black individuals lose significantly less weight than white persons during treatment, but their regain of lost weight was either equal to or smaller than white participants (Kumanyika et al., 2002; Rickel et al., 2007). Black participants lost less weight during the first 18 months of treatment in a large trial examining weight loss and blood pressure; yet, there was no longer a difference in weight loss

between the groups at 36 months (Stevens et al., 2001), suggesting that black participants experienced better weight maintenance. A smaller trial reported that weight regain was more rapid in black participants (Wing & Anglin, 1996). Others have found that a higher proportion of black persons failed to lose  $\geq 5\%$  of their initial weight (Early et al., 2007). Insufficient research has been performed with black populations to make conclusions about weight management, in particular examining weight maintenance after loss.

Little is known about members of racial minority groups like black Americans and their weight maintenance. One randomized clinical trial and three other trials addressing weight-loss maintenance with black individuals were found (Barnes et al., 2007; Kumanyika et al., 2005; Walcott-McQuigg et al., 2002). The randomized trial, conducted in an urban university's outpatient family practice department, aimed to improve weight-loss maintenance in the two interactive, culturally-oriented intervention arms (group meetings and staff-assisted self-help) compared to the usual care group, but found no difference between the groups in amount of regain. While the participants regained a nonsignificant mean of 0.3 kg (95% CI, -0.6 to 1.3 kg), the total weight loss from the beginning of the weight-loss phase was only 1.2 kg (95% CI, -0.1 to 2.3 kg) (Kumanyika et al., 2005). Findings from a weight-loss trial with 23 African American women, 10 of whom completed the weight-maintenance phase, revealed that a lower response to hunger and eating cues were marginally related to weight-loss maintenance,  $p = .057$  (Walcott-McQuigg et al., 2002). Two qualitative studies used focus groups with African American women to try to understand elements related to weight-loss maintenance. Barnes et al. noted the importance of encouragement from others as well as dealing with practical matters like hairstyle disarrangement during exercise (2007). Others reported motivations for weight-loss maintenance

that included looking better in properly-fitted clothing and feeling better about their appearance (Young, Gittelsohn, Charleston, Felix-Aaron, & Appel, 2001).

Racial differences appear to exist in the perception of an ideal body image and preference for body size. Greenberg and LaPorte surveyed 63 African American and 116 European American men and asked them to rank a sequence of different-sized female silhouettes in order of most desirable. European American men selected significantly slimmer figures and stated they hoped their girlfriends would lose weight significantly more frequently than African American men (1996). Self-perception also appears to differ between black and white women. Duncan et al. found that black, inactive women did not feel their weight, physical appearance, fitness, or eating behaviors were any worse than their white counterparts despite the fact that they weighed more, were not as fit, and had a higher percentage of fat in their diet (2003). Other studies have reported that black women have higher levels of body satisfaction at a larger body size (Baturka, Hornsby, & Schorling, 2000; Wolfe, 2000). Some research, however, questions the link to body size preference and race. A study of black and white female dieters in mid to high socioeconomic classes (mean annual income between \$50,000- \$59,999) found no significant differences in discontent with body size between minority and non-minority women; these authors suggest that previously reported racial differences may have been due to socioeconomic status rather than weight (Caldwell, Brownell, & Wilfley, 1997).

Because research in long-term weight maintenance is lacking (Jeffery et al., 2000) and little empirical evidence exists from the few studies that investigated this issue in minority populations, the dissertation study will fill an important gap in the literature by exploring any differences that may exist between black and white persons in weight maintenance after a behavioral weight-loss trial.

### **1.3.3 Low-fat diet experiences**

Research has focused on sustaining a diet low in fat as a method for promoting weight maintenance (Astrup, Grunwald, Melanson, Saris, & Hill, 2000; Lindstrom et al., 2006; Shick, Wing, Klem, McGuire, Hill, & Seagle, 1998; Swinburn, Metcalf, & Ley, 2001), but following a low-fat diet may be more difficult in the long term. High-fat foods are often considered more palatable. This palatability and lack of satiating ability (Astrup, Toubro, Raben, & Skov, 1997) have the potential to lead to overconsumption and a greater caloric intake (Bray, Paeratakul, & Popkin, 2004). In addition, individuals report feeling deprived when eating a diet low in fat (Urban et al., 1992). A study comparing the efficacy of a low-calorie diet without fat restriction to a diet limiting fat intake found similar weight losses between the two groups during treatment, and long-term weight-loss maintenance was not different between the groups, suggesting that adherence to one diet was not improved over adherence to the other (Jeffery, Hellerstedt, French, & Baxter, 1995). Others have found that improved long-term weight losses may actually result from a moderate-fat diet compared to a low-fat diet (Azadbakht, Mirmiran, Esmailzadeh, & Azizi, 2007; McManus, Antinoro, & Sacks, 2001) and that dietary adherence to a moderate-fat diet may be less difficult, resulting in better maintenance outcomes. Yet, a distaste for fat has been noted to develop in those who are adherent to a low-fat diet, promoting the continuation of the diet long-term (Urban et al., 1992). It is imperative to understand what individuals experience when following a low-fat diet in order to determine how to best promote maintenance of lost weight. Additionally, the experiences of black persons related to following a low-fat diet have not been specifically documented.

### **1.3.4 Barriers**

Multiple barriers to weight management exist in the areas of physical activity (Fulkerson, French, Story, Hannan, & Neumark-Sztainer, 2004; Jakicic, 2003) and dietary intake (Eikenberry & Smith, 2004; Vijan et al., 2005). A weight-maintenance investigation of barriers associated with physical activity and healthy food intake in women aged 18-32 years found the main barriers to healthy eating were concerns about taste, insufficient time, and motivation, and the belief that healthy foods cost more; principle barriers to physical activity were lack of time and motivation and exercise facilities that were too expensive (Andajani-Sutjahjo, Ball, Warren, Inglis, & Crawford, 2004). The PREFER investigation found that change scores in the Barriers to Healthy Eating Scale (decreases in barriers) were significantly correlated with weight loss at 6 months (Burke, Styn, Elci, Music, & Warziski, 2007). Barriers for weight loss in African American women include the cost associated with healthy foods and exercise participation (Davis, Clark, Carrese, Gary, & Cooper, 2005; Eyler, Baker, Cromer, King, Brownson, & Donatelle, 1998), as well as traditionally-prepared cultural foods and eating expectations of family members (Airhihenbuwa, Kumanyika, Agurs, Lowe, Saunders, & Morssink, 1996; Carter-Edwards, Bynoe, & Svetkey, 1998). Barriers to healthy eating for weight maintenance need to be further explored in minority populations who likely have more obstacles to overcome, e.g., higher prevalence of fast food restaurants and fewer supermarkets in communities with a high proportion of minority persons (Block et al., 2004; Morland et al., 2002).

### **1.3.5 Social support**

Social support, relationships intended to provide positive strength to the recipient (Peterson & Bredow, 2004), is an identifiable influence on behavior (Steptoe, Wardle, Pollard, Canaan, & Davies, 1996). Some studies have reported improved outcomes in dietary modification and weight-loss treatment (Kelsey, Earp, & Kirkley, 1997; McLean, Griffin, Toney, & Hardeman, 2003; Verheijden, Bakx, van Weel, Koelen, & van Staveren, 2005), and some descriptive findings indicate that social support is important for successful maintenance (Elfhag & Rossner, 2005; Kayman et al., 1990). However, social support in weight maintenance has been largely unexplored. Wing and Jeffery examined the influence of social support on both weight loss and maintenance and found that recruiting participants with friends and increasing social support was of significant benefit. Among those recruited alone and assigned to standard behavioral treatment only, 76% completed the 4-month treatment, and 24% maintained their lost weight after 6 months. In contrast, in the group recruited with friends/family and assigned to standard treatment with social support added, 95% completed treatment and 66% maintained their lost weight at 6 months post-intervention. Notably, participants in the added social support groups received financial incentives for maintaining 100% of their lost weight, and the findings of this study might be confounded by that aspect (Wing & Jeffery, 1999). In the African American community, because of a cultural pressure to be accepting of one's body, obese women had conflicting feelings about body image and weight and thought that they did not have the social support necessary for weight loss (Baturka et al., 2000; Walcott-McQuigg et al., 2002). A comparison of perceptions and behaviors associated with diet and physical activity in urban African American women and rural Caucasian women found that rural Caucasian women stated they had more social support for changing their behaviors (Nothwehr, 2004). Alluding to the

important role of social support, married participants lost more weight than those who were single in a weight-loss study including only African Americans (Kumanyika et al., 2005).

### **1.3.6 Stress**

Stress has been shown to have a significant impact on weight management and eating behaviors (Crowther, Sanftner, Bonifazi, & Shepherd, 2001; DePue et al., 1995). Korceila and colleagues found that a high stress level at baseline was predictive of weight gain over a 6-year time frame (1998). Low levels of stress were associated with weight-loss maintenance in men (Sarlio-Lahteenkorva, Rissanen, & Kaprio, 2000). The physiologic effects of stress have been documented by increased levels of cortisol (Koo-Loeb, Costello, Light, & Girdler, 2000), which can increase hunger and eating (Newman, O'Connor, & Conner, 2007; Tataranni, Larson, Snitker, Young, Flatt, & Ravussin, 1996). Women who react to stress with high cortisol secretion were found to not only eat more while recovering from stress, but also choose sweet foods (Epel, Lapidus, McEwen, & Brownell, 2001). Stress-induced cortisol secretion is also associated with central body fat deposition (Epel et al., 2000; Gluck, Geliebter, & Lorence, 2004), a known cardiovascular risk factor (Bjorntorp, 1997). Physical responses to stress — heart rate and blood pressure — were measured after mentally challenging tests in 22 older African Americans, and researchers found that those with more central body fat had significantly greater heart rate and blood pressure increases than those with a smaller waist circumference (Waldstein, Burns, Toth, & Poehlman, 1999). A mixed methods investigation of 36 African American women found that women who were more overweight had higher stress levels, and more than half felt that stress negatively impacted their weight management behavior (Walcott-McQuigg, 1995). Others have investigated chronically-stressed caregivers of Alzheimer's patients compared to age-matched

controls and found that 31% of caregivers had a marked increase in weight ( $\geq 1$  BMI unit) over 15 months compared to 11% of control participants with a marked increase (Vitaliano, Russo, Scanlan, & Greeno, 1996).

### **1.3.7 Dietary intake**

Research findings indicate that dietary behaviors of racial minorities may differ from those of non-minorities including an increased intake of fat and calories (Haire-Joshu, Brownson, Schechtman, & Nanney, 2001; Oster & Thompson, 1996) and decreased intake of sources of fiber, such as fruits and vegetables (Jen, Brogan, Washington, Flack, & Artinian, 2007; Satia-Abouta, Galanka, Potter, Ammerman, Martin, & Sandler, 2003; Zenk et al., 2005). A cholesterol screening and education study of dietary intake related to fat consumption found that Whites had the lowest fat diet, as measured by the Food Habits Questionnaire, followed by Hispanics and then Blacks. Additionally, black and Hispanic participants were more likely to fry foods than white participants, and Hispanics were least likely to read food labels, which would increase awareness of calorie and fat content (Gans, Burkholder, Risica, & Lasater, 2003). An investigation of food preferences among three generations of black and white women found that black participants significantly preferred foods such as pancakes, grits, fried meat, french fries, cheese sandwiches, and fruit pies than did their white counterparts. This study also found that the preferences of the third generation of black women related more to their previous two generations than with the third generation of white participants (Dacosta & Wilson, 1996). These cultural differences may play an intricate role in weight maintenance for minority populations.



### **1.3.8 Physical activity**

Many studies have reported the need for increased physical activity to maintain weight loss (DePue, Clark, Ruggiero, Medeiros, & Pera, 1995; Schoeller, Shay, & Kushner, 1997; Votruba, Horvitz, & Schoeller, 2000; Wadden, Vogt, Foster, & Anderson, 1998; Wier, Ayers, Jackson, Rossum, Poston, & Foreyt, 2001). Routine physical activity is one of the best predictors of continued weight maintenance after weight loss; moreover, regular physical activity decreases cardiovascular disease risk and increases quality of life in many overweight persons (Lavie & Milani, 1997; McInnis, 2000; Penedo & Dahn, 2005). Rather than only scheduled exercise, physical activity experts advocate increases in activity during daily life routines, such as increased walking or stair climbing (U.S. Department of Health and Human Services, 1996). Recommendations for overweight and obese persons include gradually increasing moderate intensity physical activity to at least 150 minutes per week, but for long-term maintenance of weight loss, 200-300 minutes per week should be achieved (Jakicic et al., 2001). In fact, updated recommendations from the American College of Sports Medicine and American Heart Association specify that in order to prevent weight regain, persons should engage in 60-90 minutes of moderate-intensity physical activity each day (Haskell et al., 2007; U.S. Department of Health and Human Services, 2005). Fortunately, research has demonstrated that activity can be accumulated throughout the day rather than performed in one continuous period and remain beneficial for weight management and fitness (Jakicic, Winter, Lang, & Wing, 1999). A recent study of weight-loss maintenance one year after a behavioral weight-loss intervention reported that 80% were successful at maintaining at least 5% of lost weight, but 44% of the maintainers reported between 1-30 minutes of daily activity and only 23% reported between 31-60 minutes of daily activity. The maintainers did consume an average of 384 fewer daily calories, suggesting

that weight maintenance might be achieved without meeting physical activity recommendations by reducing caloric intake (Cox et al., 2007). The dissertation study will examine physical activity as a potential mediator of long-term weight maintenance.

## **1.4 PRELIMINARY STUDIES**

The PI has conducted research with the PREFER data to learn more about the sample population and areas of interest in the dissertation study including self-efficacy and potential differences weight maintenance between minorities and non-minorities. She has also participated in research examining barriers to healthy eating, the experiences associated with following a low-fat diet, the eating habits of individuals interested in weight-loss treatment, adherence to the weight-loss treatment protocol, differences in binge eating scores, self-monitoring diet and exercise, and the effect of treatment preference and the LOV diet on weight loss. Findings from studies pertinent to the variables in this proposal are summarized below. Related publications are listed after the study summaries. The published paper on self-efficacy, dietary adherence, and weight loss (Study 1) is included in Appendix A.

### **1.4.1 Study 1. The impact of changes in self-efficacy and adherence on weight loss**

The PI conducted a secondary analysis to evaluate the influence of self-efficacy for resisting eating and dietary adherence on weight change over time in the PREFER study. The purpose was to determine whether an increase in self-efficacy and higher dietary adherence were associated with weight loss, and whether self-efficacy remained associated with weight loss after

controlling for dietary adherence. The mean weight loss at 18 months was approximately 5% of baseline weight and the mean increase in self-efficacy was nearly 12%. Self-efficacy, based on the total score of the Weight Efficacy Lifestyle (WEL) Questionnaire, improved over time ( $p = .04$ ) and was associated with weight loss ( $p = .02$ ), with the greatest increase in self-efficacy occurring at 6 months, the time point of the largest mean weight loss. Fat gram adherence was associated with weight loss ( $p < .001$ ), and self-efficacy remained associated with weight loss after controlling for fat gram adherence over time ( $p < .001$ ). In addition, an examination of the five subscales of the WEL revealed that all subscales were associated with weight loss,  $ps < .006$ .

*Implications for this proposal:* This secondary analysis allowed the PI to examine the relationship of self-efficacy for resisting eating with weight loss in the sample of participants for the dissertation study. This study increased the PI's knowledge related to a potential predictor of weight maintenance, self-efficacy, as measured by the instrument to be used, the WEL. It required the use of advanced statistical techniques, mixed effects modeling, and allowed the PI to perform preliminary data screening and analytic techniques in preparation for the dissertation analysis. It also exposed the PI to the rigorous standards of publishing manuscripts and the persistence needed to achieve publication. The finding that self-efficacy was related to weight loss over time supports the investigation of self-efficacy as a predictor of weight-loss maintenance.

Warziski, M., Sereika, S.M., Styn, M.A., Music, E., Burke, L.E. (2008). Changes in self-efficacy and dietary adherence: The impact on weight loss in the PREFER study. *Journal of Behavioral Medicine*, 31, 81-92.

#### **1.4.2 Study 2. Weight-loss maintenance for minorities and non-minorities during PREFER**

The PI conducted a secondary analysis of 12- to 18-month weight changes during the 6-month, no-contact maintenance period of the PREFER study to determine if there were differences in weight-loss maintenance between minority and non-minority participants. The sample, consisting of participants who had weight data for the 12- and 18-month assessments ( $N = 124$ , non-minorities  $n = 87$ , minorities  $n = 37$ ), was mostly female (86%) with a mean age of 44.8 years ( $SD = 8.4$ ) and 15.4 ( $SD = 2.6$ ) years of formal education. Sociodemographic variables (age, gender, education, income) and baseline weight were not different between the minorities and non-minorities,  $ps > .05$ . There was no difference in absolute weight change in kilograms ( $p = .93$ ) or percent weight change between the two groups during the 12- to 18- month maintenance phase ( $p = .82$ ). At 18 months, minorities had regained a mean ( $SD$ ) of 3.7% (3.9%) of their 12-month weight, and non-minorities had regained a mean 3.3% (4.1%).

*Implications for this proposal:* This analysis resulted in pilot data for the sample size analysis and effect sizes computations for the dissertation study. It allowed the PI to examine the primary variable of interest, weight-loss maintenance between minorities and non-minorities, during a shorter time interval, and to explore sociodemographic variables in the sample. While these data suggest that a difference in maintenance might not exist, they only provided information for a 6-month period while participants were actually still enrolled in the PREFER study, and conclusions cannot be drawn about maintenance at the 18-month time point of the dissertation study.

Warziski, M., Sereika, S.M., Styn, M.A., Elci, O.U., Burke, L.E. (2007). Does weight-loss

maintenance differ for minorities compared to non-minorities? *Circulation*, 115(Suppl. 8), e243.

### **1.4.3 Study 3. The impact of barriers to healthy eating on weight loss**

The scores from the Barriers to Healthy Eating Scale were examined in the PREFER study to determine if reported barriers influenced weight loss over time. Total scores and subscale scores (emotions, daily mechanics of following the eating plan, social support) were examined as correlates of weight loss at 6, 12, and 18 months. The emotions and daily mechanics subscales as well as the total score decreased significantly at 6 months, which coincided with the time point of the largest weight loss. Nonsignificant increases in barriers were observed at 12 and 18 months. Analysis revealed that a significant relationship existed between a decrease in reported barriers to healthy eating and weight loss over time,  $p < .01$ .

*Implications for this proposal:* This study revealed that barriers to following a healthy eating plan were associated with weight loss in the parent study and supports examining this variable as a predictor of long-term weight maintenance. Because a slight increase in barriers was noted during the 12-18 month maintenance period of PREFER, this finding might suggest an increase in barriers will be observed at the dissertation study time point and could impact weight regain.

Burke, L.E., Styn, M.A., Elci, O.U., Music, E., Warziski, M. (2007). How do barriers to healthy eating impact weight loss? *Circulation*, 115(Suppl. 8), e246.

#### **1.4.4 Study 4. The influence of experiences following a low-fat diet on weight loss**

The purpose of this study was to investigate participants' experiences while following a low-fat diet and determine if there were differences between the standard and vegetarian diet groups in the PREFER study as well as to examine the relationship with weight change. The Experiences Associated with Following a Low-Fat Diet Scale (ELF) was first administered in the PREFER study at the 6-month time point, rather than at baseline, after the participants had been following the assigned diet. The total scores as well as the scores for the subscales wellness and distaste decreased significantly over time for the total sample ( $ps < .03$ ), and the wellness score decreased significantly more in the standard diet group at 12 months. The total ELF score significantly predicted weight change at each time point, ( $ps = .001$  to  $.05$ ).

*Implications for this proposal:* This preliminary study used the same instrument that is included in the dissertation study and reported that a relationship exists between dietary experiences when consuming a low-fat diet and weight loss. Through the analysis, the PI was involved in the details related to coding and scoring this instrument. Although the total score was predictive of weight loss in the parent study, these results suggest that positive experiences associated with eating low-fat foods decrease over time and are supportive of exploring this variable in the maintenance of weight loss.

Burke, L.E., Styn, M.A., Elci, O.U., Sereika, S.M., Music, E., Warziski, M. (2007). Experiences following a low fat diet influence dietary maintenance. *Annals of Behavioral Medicine*, 33 (Suppl.), S186.

## **1.5 RESEARCH DESIGN AND METHODS**

### **1.5.1 Introduction**

The dissertation study will employ a prospective, descriptive design to explore the factors related to weight maintenance after an 18-month behavioral weight-loss intervention, the PREFER study. Participants who complete the final assessment of the PREFER study will be recruited to participate in an investigation of weight maintenance. Sixteen months after completing the parent study, participants will be sent letters asking them to complete six questionnaires and return for one additional appointment to obtain their weight as measures of a long-term follow-up to the PREFER study. Persons may be uncomfortable returning if they have gained weight so an emphasis will be placed on the interest of exploring influencing factors related to weight management. Dr. Stephen Thomas, Director of the Center for Minority Health, will provide guidance in developing culturally sensitive messages to ensure a high rate of return for minority participants.

### **1.5.2 Description of the Parent Study**

In the PREFER study, 182 participants were recruited in three cohorts, stratified on race and gender, and randomized to treatment Preference-Yes or treatment Preference-No. Those randomized to treatment Preference-Yes were assigned to their preferred diet plan (standard fat- and calorie-restricted or standard fat- and calorie-restricted diet + LOV); those randomized to treatment Preference-No were then randomized again to the standard diet or the LOV diet. During the 12-month active intervention, participants maintained weekly food and physical

activity records and weights were measured at each intervention session; a 6-month maintenance period followed with no sessions. Participants in PREFER were mainly female (87.4%) and white (70.5%) with an average age of 44.1 years (range 20-55 years) and an average BMI of 33.94 kg/m<sup>2</sup> (range 26.7-42.6 kg/m<sup>2</sup>). Each treatment group received the same behavioral intervention and followed a calorie-restricted (1200 kcal for those weighing < 200 lbs and 1500 kcal for ≥ 200 lbs) and fat-restricted (25% of daily calories) diet for 18 months; the lacto-ovo-vegetarian group eliminated all meat, fish, and poultry over the first 6 weeks. Baseline, 6-, 12-, and 18-month physical assessment measures included weight, BMI, waist circumference, serum collection for lipid profile, glucose, and insulin. Paper-and-pencil measures, administered at 6, 12, and 18 months, included a Three-Day Food Diary, Paffenbarger Activity Questionnaire, Barriers to Healthy Eating, Hunger Satiety Scale, Weight Efficacy Lifestyle Questionnaire, Beck Depression Inventory-II, and Medical Outcomes Questionnaire, Short Form-36. The Experiences Associated with Following a Low-Fat Diet is first administered at the 6-month assessment, rather than baseline, after the participant has been exposed to a reduced-fat diet.

### **1.5.3 Eligibility Criteria**

The eligibility criteria for the dissertation study are dictated by the selection criteria of the PREFER study; participants were 18-55 years old at enrollment of the PREFER study, agreeable to randomization to their treatment preference or not and one of the two diet plans, had a BMI between 27 and 43 kg/m<sup>2</sup>, inclusively, and had adequately completed a 5-day food intake diary. The age range was chosen to ensure an adult population that was young enough to have a limited occurrence of comorbidities, such as osteoarthritis, that might prohibit participation in physical



activity. For the dissertation study, participants must also have completed the final 18-month assessment of the PREFER study.

#### **1.5.4 Recruitment**

At the final assessment of the PREFER study in the end-of-study survey, most participants indicated an interest in participating in future investigations. Former PREFER participants will be recruited to participate in the dissertation study of weight maintenance. Because the PI has been working as a member of the PREFER study research team, a relationship with the participants has developed and recruitment will be by an individual known to them. Eligible participants will receive a letter from the PI of the PREFER study and the PI of the dissertation study, and a consent form approximately 16 months post-completion of the PREFER study. While 16 months is a long time, contact with participants has been maintained by the PREFER study through birthday and holiday cards; participants also received their laboratory results 2 months after the study's completion. The letter will explain the interest in exploring the factors involved in weight maintenance and ask that they return for one assessment. To encourage participants who may be reluctant to respond because they have gained weight, the letter will stress the interest in examining variables related to weight management regardless of current weight. The purpose of learning about weight maintenance and how to better assist persons in this endeavor will be emphasized. See Appendix E for the letter. Interested participants will be asked to call for more information. During the phone call, the study will be explained to the participant, and the person will be asked if he/she has any questions about the consent form. See Appendix D. Consent forms will be returned by mail and participants will be mailed the questionnaires and contacted to schedule an appointment for their weight after the consent form

is received. A copy of the consent form will be given to the participant at their appointment. Written informed consent will be obtained, per the protocol of the Institutional Review Board (IRB) at the University of Pittsburgh, to allow the use of secondary data from the PREFER study as well as to collect additional measures. If persons are unable to return to Oakland, the PI will discuss alternative means to obtain their weight such as traveling to their place of business, home, or another mutually agreed upon location. As a last resort, for persons who absolutely cannot meet in person, the PI will obtain a current, self-report weight. Self-reported weights have been used in the National Weight Control Registry since 1994 (Wing & Hill, 2001) and have been shown to be accurate by others (Kuczmarski, Kuczmarski, & Najjar, 2001; Must, Willett, & Dietz, 1993; Palta, Prineas, Berman, & Hannan, 1982). Participants will be compensated for their time with a gift certificate to a regional grocery store chain. The PREFER study had a 76% retention of participants at the final assessment ( $N = 132$ , non-minorities  $n = 92$ , minorities  $n = 40$ ). Due to the high retention of the PREFER study and because the population of Pittsburgh tends to be stable with persons maintaining their residency, the projected loss of participants for the dissertation study is an additional 10% beyond that of the PREFER study. Based on PREFER study retention, a projected recruitment of 119 participants is expected, maintaining the 29.5% minority composition (84 non-minorities, 35 minorities).

#### **1.5.5 Measurement of Dependent Variable (Instruments are located in Appendix C):**

All measurements will be conducted at one time point at the outpatient department of the Clinical and Translational Research Center at Montefiore University Hospital or the School of Nursing in a private room. If participants are unable to travel to Oakland, arrangements will be made to meet the participant at an agreeable, convenient location, e.g. their home, work place.

As a last resort, for participants who are absolutely unable to meet in person, we will obtain a self-reported current weight, which has been shown to be valid in previous studies of middle-aged adults (Kuczmarski et al., 2001; Spencer, Appleby, Davey, & Key, 2002). Often a 2 kg correction is added to self-reported weights to account for potential under-reporting (Kramer, Jeffery, Snell, & Forster, 1986; Linde, Jeffery, Finch, Ng, & Rothman, 2004; Palta et al., 1982), and this correction will be added to self-reported weights in the dissertation study.

*Weight change.* % weight change from completion of the PREFER study to 18 months post completion will be the primary dependent variable and calculated as follows:

$$\frac{\text{weight at 18 months} - \text{PREFER study completion weight}}{\text{PREFER study completion weight}} \times 100 = \% \Delta \text{ weight (weight change)}$$

The Tanita Scale and Body Fat Analyzer will be used to measure weight in pounds with participants wearing light clothing and standing bare foot on the scale's footpads. The Tanita uses leg-to-leg bioelectrical impedance analysis to measure body composition and has been validated with underwater weighing and seven skinfold measures (Powell et al., 2001).

### **1.5.6 Measurement of Potential Mediators**

*Dietary intake.* In place of the 3-Day Food Diary used in the PREFER study, two unannounced 24-hour dietary recalls will be conducted for two reasons. The recall is less burdensome for the participant than completing the food diary, and the recall is the most robust method for collecting dietary intake data (Conway, Ingwersen, & Moshfegh, 2004; Freedman et al., 2004). The two recalls will include a nonconsecutive workday and non-working day that preferably are

representative of their typical food intake. The interviewer will use the Nutrition Data System Research (NDSR) software, which prompts a thorough review of foods eaten in the previous 24 hours. Participants will be instructed on how to complete the dietary recall and will be provided measurement references for use during the interview to help them judge their portion sizes. Participants will be told to expect a call twice within the two weeks prior to or following the assessment. The NDSR software is maintained by the Nutrition Coordinating Center at the University of Minnesota (Buzzard, Schakel, & Ditter-Johnson, 1995), contains over 18,000 foods, 8000 brand name products, a number of ethnic foods and is updated twice a year to include new foods and data. The dietary data obtained from the PREFER study via 3-Day Food Diaries were also analyzed using this same nutrient software. An average kilocalorie (kcal) and fat gram intake of the two days will be derived.

*Physical activity.* The Paffenbarger Activity Questionnaire (PAQ) will be used to measure physical activity (Paffenbarger et al., 1978) and asks participants about their usual activities for the past week. It provides an estimation of kcal expenditure through the assessment of leisure-time activities e.g., daily city blocks walked, number of flights of stairs climbed, total minutes of sports or recreational activities. In the scoring of the PAQ, one city block = 8 kcal, one flight of stairs = 4 kcal, and sports or recreational activities are assigned a metabolic equivalent or MET value based upon intensity. A MET is defined as the ratio of an individual's working metabolic rate relative to the resting metabolic rate. One MET is equal to 1 kcal per kg per hour and is the caloric consumption of a person while at total rest (Ainsworth et al., 1993). Example MET values include light intensity = 5 kcal/min, moderate intensity = 7.5 kcal/min, and vigorous intensity = 10 kcal/min ("Paffenbarger Physical Activity Questionnaire: A collection of

physical activity questionnaires for health related research," 1997). A total weekly score for energy expenditure in kcals is derived from the equation:

$$(\text{blocks/day} \times 8 \text{ kcal/block} \times 7 \text{ days/week}) + (\text{flights of stairs/day} \times 4 \text{ kcal/flight} \times 7 \text{ days/week}) + (\text{MET value for recreational activity} \times \text{occasions/week} \times \text{minutes/occasion}) = \text{Total kcal/week}$$

This instrument has shown good test-retest reliability ( $r = .34$  to  $.72$ ); validity has been reported as  $r = .29$  with Caltrac Physical Activity Monitors and  $r = .62$  with VO2 max (Ainsworth et al., 1993).

### 1.5.7 Measurement of Predictor Variables

*Experiences Associated with Following a Low-Fat Diet (ELF)*. This questionnaire is a 25-item scale developed and used in the Women's Health Trial (Urban et al., 1992) and measures experiences believed to be related to dietary maintenance. Of the 6 factors in the scale, two are indicators of experiences associated with maintaining a low-fat diet— *wellness* (feeling healthier while on the diet) and *distaste* (for fat). The remaining four factors are believed to inhibit maintenance— *cost* (time and money), *inconvenience* (adhering to the diet when not eating at home), *deprivation* (denied desired foods), and *family* (insufficient support from family). It has a 5-point scale (1 = strongly disagree to 5 = strongly agree) and was validated during the Women's Health Trial ( $r = .26$  to  $.76$ ). Negatively worded items are reverse coded so that higher scores represent a more positive experience. The PREFER study's psychometric analysis showed Cronbach's alpha to be .83 in a sample of predominantly middle-aged women (Kim, Burke, Music, Cartwright, Polakoski, & Tschirpke, 2004).

*Barriers to Healthy Eating (BHE)*. This scale is a 22-item questionnaire in which participants rate various circumstances related to following the healthy eating plan (emotions,

daily mechanics of following the eating plan, social support) on a scale of 1 (no problem) to 5 (very important problem). Lower scores indicate fewer barriers. This scale was used in a previous weight-loss study (Jeffery et al., 1993) but was expanded by the PI of the PREFER study and psychometric testing using a sample of mostly women of middle age revealed a Cronbach's alpha of .86; test-retest reliability across four time points was acceptable with an intraclass correlation of .89 (Burke, Kim, & Music, 2004).

*Weight Efficacy Lifestyle (WEL) Questionnaire.* This instrument is a 20-item measure to assess self-efficacy for weight management (Clark, Abrams, Niaura, Eaton, & Rossi, 1991). This scale assesses one's confidence in the ability to resist eating in different situations on a scale of 0-9, with higher scores indicating higher confidence. The five subscales include availability, negative emotions, physical discomfort, positive activities, and social pressure. Psychometric properties are well-established in samples of over 70% women in their early 40's with Cronbach alpha coefficients ranging from .70 to .90 (Clark et al., 1991). The validity and reliability of the instrument has also been established in middle-aged African American women (Dutton, Martin, Rhode, & Brantley, 2004). The pilot study conducted by the PI using this instrument found that self-efficacy was significantly associated with weight loss (Warziski et al., 2007).

*Self-Efficacy for Exercise (SEE) Scale.* This questionnaire, not administered during the PREFER trial, is a 9-item self-efficacy measure for exercise (Resnick & Jenkins, 2000) that asks persons to rate their confidence in their ability to exercise 3 times per week for 20 minutes given a variety of circumstances. Good internal consistency with a sample of older, predominantly female adults (mean age = 85 years) has been reported with Cronbach's alpha = .92; construct and criterion-related validity have been supported as well (Resnick & Jenkins, 2000). The scale range is 0 (not confident) to 10 (very confident), and the measure is scored by totaling the

response rating for each item and dividing by the number of items answered with higher scores indicating greater confidence. Successful weight-loss maintainers have been shown to have significantly greater confidence in the ability to exercise (Riebe et al., 2005; Teixeira et al., 2004).

*Behavioral Strategy Survey (BSS).* This scale is a 20-item questionnaire constructed for the dissertation study to assess strategies utilized (or not) for weight maintenance. It asks about standard behavioral strategies taught during the PREFER study intervention such as self-monitoring of food intake and physical activity, increasing physical activity, portion control, eating and assertiveness, label reading, recipe modification, monitoring eating and exercise cues in your environment, problem-solving for high-risk situations, negative thoughts, stress management, and relapse prevention. Each question asks the participant to estimate, on a 0-100% scale, what percent of the time in the last 18 months the strategy was used. This survey was not administered during the PREFER trial but was pilot tested in a group of women being counseled for weight loss who reported that it was easily completed. See Appendix C.

*Social support.* In order to reduce subject burden and avoid adding additional instruments, the first secondary aim exploring social support will be assessed using three items from the Barriers to Healthy Eating Scale and four items from the Experiences Associated with Following a Low-Fat Diet Scale that measure family and friend social support. Each instrument uses a five-point scale and a composite score will be calculated for social support. One item in the Behavioral Strategy Survey asks about social support for healthy eating and physical activity as well.

*Stress.* The second secondary aim examining stress will be assessed in the Behavioral Strategy Survey, which inquires about stressful life events, how stress affects eating habits, and

stress management techniques. This variable was not measured in the PREFER study and data will serve as a concurrent predictor of weight maintenance.

With the exception of the WEL questionnaire, these instruments have not been specifically tested for psychometric properties among black persons, but have been tested with samples that included black participants.

**Table 1.1: Time Points for Assessment of Variables of Interest**

Variable	Completion of PREFER	Dissertation Study
Weight	X	X
Dietary intake	X	X
Physical activity	X	X
BHE	X	X
ELF	X	X
WEL	X	X
SEE		X
BSS		X
Social support	X	X
Stress		X

*Note.* BHE= Barriers to Healthy Eating Scale; ELF= Experiences Associated with Following a Low-Fat Diet Scale; WEL= Weight Efficacy Lifestyle Scale; SEE= Self-Efficacy for Exercise Scale; BSS= Behavioral Strategy Survey



### 1.5.8 Procedures

Participants will be mailed questionnaires after they have returned the consent form and asked to bring the completed paper work with them to the assessment appointment. Questionnaires will be reviewed for missing data and any ambiguous responses will be clarified. If the participant forgets the questionnaires, they will be completed at the assessment appointment. This protocol was followed in the PREFER with successful collection of data. All questionnaires for the dissertation study were administered during the PREFER study with the exception of the Self-Efficacy for Exercise Scale and the Behavioral Strategy Survey. Questionnaires will be in Teleform format and scanned using Teleform Elite (version 8.2, Verity, Inc., Sunnyvale, CA), a Windows-based software package for automated data entry/verification (Davidson, Ryan, Rohay, & Sereika, 1996). Questionnaire forms will be pre-coded to help decrease coding error during data entry; range checking and data cleaning will be performed prior to analysis.

**Table 1.2: Dissertation Study Timeline for Questionnaire Administration, Assessment of Weight and Dietary Intake**

	Cohort 1	Cohort 2	Cohort 3
PREFER Study Completion	Aug. 2004	Feb. 2005	Aug. 2005
Dissertation Study Data Collection	Feb. 2006	Aug. 2006	Feb. 2007

## **1.6 DATA ANALYSIS PLAN**

### **1.6.1 Preliminary Data Analysis**

A detailed descriptive analysis of all data collected will be performed involving the summarization of data and the use of inferential and graphical exploratory data analytic techniques. The information obtained from this preliminary investigation of the data will be used to: 1) describe univariate and bivariate sample distributions of the data; 2) identify the interrelationships between variables; and 3) check for the violation of assumptions underlying identified statistical techniques, for example normality of model errors and presence of outlying values. The possible existence of univariate and multivariate outliers will be assessed in order to avoid distortion of descriptive or test statistics, type I or type II errors, and/or results that are not generalizable to the population of interest. Sensitivity analyses will be performed without outlying values to determine the outliers' influence on the results. If outliers are determined to overly influence results, these values will be excluded from the analysis and the outliers will be completely described or steps will be taken to minimize their influence, e.g., data transformations. If additional statistical assumptions are severely violated, data transformations or more statistically robust procedures (i.e., nonparametric methods) will be used. Also to be examined: (a) comparability of racial groups, (b) the need for covariate adjustment, (c) population representativeness of the sample as a result of dropouts, and (d) the internal consistency and validity of established scales. The internal consistency of scales will be estimated using Cronbach's coefficient alpha.

### 1.6.2 Primary Aim #1

Investigate if there are differences between black and white persons in the percentage of weight change at 18 months post-completion of the PREFER study as well as successful weight maintenance defined as  $\leq 10\%$  weight regain.

*Analysis.* Percentage of weight change at 18 months post-completion of the PREFER Trial will be calculated and expressed as a percentage of the weight change relative to weight at the completion of the PREFER study by the following equation:

$$\frac{\text{weight at 18 months} - \text{PREFER study completion weight}}{\text{PREFER study completion weight}} \times 100 = \% \Delta \text{ weight (weight change)}$$

Negative scores will indicate weight loss; positive scores will indicate weight gain. Additionally, a binary variable to indicate  $\leq 10\%$  regain over 18 months (yes=0, no=1) will be derived to indicate successful long-term weight maintenance. Appropriate descriptive statistics will be computed for the total sample and the black and white participants. The percentage change in weight will be summarized using means, standard deviations, medians, and ranges, while the indicator for weight regain will be summarized using frequency counts and percentages. Provided the data for the percentage weight change are normally distributed and because the groups are independent, two sample *t*-tests will be used to determine any significant differences in weight change between racial groups. If heterogeneity of group variances is suggested by the Levene test, an independent-sample *t*-test using separate estimates of the group variances will be used. If the data are not normally distributed, the non-parametric Mann-Whitney U test will be used. For the binary version of weight maintenance, contingency table analysis using chi-square tests of independence will be used to compare the proportions of successful/

unsuccessful participants between the racial groups. If sparse cells are present (observed count < 5), Fisher's exact chi-square statistic will be used. Lastly, if covariates are identified through data screening, multiple linear regression analysis (or logistic regression for the binary outcome) will be used to adjust for the effects of covariates. Regression models will be built hierarchically with covariates added in the first block, and a dummy coded variable for race (White = 0, Black = 1) will be added in the second block to determine the effect of race on weight maintenance after controlling for the effects of covariates. The statistics examined in the linear regression models will be the change in  $R^2$  for the improvement in prediction from one model to the next, the estimate and standard error of the estimate. The improvement in the chi-square statistic will be examined when using the logistic regression. If sparse cells are present (observed count < 5) in the logistic regression, exact estimation algorithms will be used. Model fit will be assessed through the use of residual analysis and influential diagnostics. For the logistic regression, goodness-of-fit statistics, e.g. Hosmer-Lemeshow goodness-of-fit test, will be assessed to determine the fit of the model.

### **1.6.3 Primary Aim #2**

To describe the behavioral strategies utilized by black and white persons for weight maintenance.

*Analysis.* Based on the Behavioral Strategy Survey, descriptive statistics (means, standard deviations, medians, ranges) will be used to report on percentage of the time over the previous 18 months that each behavioral strategy was used. The total sample will be stratified (by Blacks vs. Whites, successful vs. unsuccessful participants as well as successful vs. unsuccessful within each racial group) and descriptive statistics (means, standard deviations, medians, ranges) will be

presented for the percentage of time that each strategy was used by each group. For both the total sample and each group, interval estimates (95% confidence interval) will also be computed.

#### **1.6.4 Primary Aim #3**

To examine the influence of predictors (experiences in following a low-fat diet, barriers to healthy eating, self-efficacy) on percent weight change and successful weight maintenance as well as whether race moderates the relationship between predictors and weight maintenance.

*Analysis.* Percentage change scores (completion of PREFER to 18 months) will be calculated for the predictors measured by the questionnaires used in the PREFER study, and the score for the one-time measure, Self-Efficacy for Exercise, will be used as a concurrent predictor. Predictors will be examined individually first using simple linear regression in order to select discriminating variables and identify a parsimonious model. Assuming normality of the residuals, homoscedasticity of error variance, independence of observations, and linearity of variables, hierarchical multiple linear regression will then be used to identify factors that predict percentage weight change. This technique permits inspection of possible confounding variables while examining principal relationships of interest. (Munro, 2005). If identified through data screening, potential covariates such as income, education, and age will be added first in the first block; the predictor variables of interest, i.e., low-fat diet experiences, barriers to healthy eating, self-efficacy (diet and exercise), will be treated as continuous variables and added in the second block. Race will be dummy coded and added in the third block to determine its effect on weight maintenance after controlling for other variables. In the fourth block, interactions between racial group and each predictor will be considered to investigate possible effect modification (i.e., moderation) due to race. Higher order effects for predictor variables (i.e., cubic or quadratic

terms) will also be explored in order to improve fit and prediction. Additionally, weight maintenance will be examined using a binary outcome; participants will be dichotomized into “regainers:  $> 10\%$  weight regain” and “maintainers:  $\leq 10\%$  regain.” Any participants who have lost further weight will be considered maintainers as they will also have had a  $\leq 10\%$  regain. Using multiple binary logistic regression in a hierarchical fashion, as described above for linear regression, the impact of the predictors (and possible higher order effects) will be examined, controlling for possible covariates and considering possible interactions with racial group. The statistics examined in the linear regression models will be the change in  $R^2$  for the improvement in prediction from one model to the next, the estimate, and standard error of the estimate. The improvement in the chi-square statistic will be examined in the logistic regression. If sparse cells are present (observed count  $< 5$ ) in the logistic regression, exact estimation testing will be used. Model fit will be assessed through the use of residual analysis and influential diagnostics. For the logistic regression, goodness-of-fit statistics, e.g. Hosmer-Lemeshow, will be assessed to determine the fit of the model.

### **1.6.5 Secondary Aim #1**

To explore the role of social support in weight maintenance for black and white persons.

*Analysis.* Social support will be measured in the 3 items from the Barriers to Healthy Eating Questionnaire and 4 items in the Experiences in Following a Low-fat Diet Questionnaire, as determined by factor analysis (Burke et al., 2004; Urban et al., 1992). A composite score will be calculated from the seven items and described using appropriate descriptive statistics for the total sample and each group. In order to avoid multicollinearity with the Barriers and Experiences scores and assuming the need for covariate adjustment in the first block, multiple

linear and multiple binary logistic regression models, as discussed above for Primary Aim #3, will be estimated considering percent change in social support in the second block by itself as a separate predictor. Race will then be added to the third block to determine its effect on weight maintenance after controlling for other variables. In the fourth block, interactions between racial group and social support will be considered to investigate possible effect modification (i.e., moderation) due to race.

#### **1.6.6 Secondary Aim #2**

To describe the impact of stress on weight maintenance for black and white persons.

*Analysis.* Stress will be analyzed descriptively using four items from the Behavioral Strategy Survey. Frequencies will be calculated regarding the percentage of time participants reported that stress influenced their eating and the percentage of time that stress-reducing techniques were used. Descriptive frequencies will also be used to analyze the stressful life events reported and the effect scores of the stressful life event(s) on eating habits. A mean score for each of the three continuous items will be computed. Multiple linear and multiple binary logistic regression models, as discussed above for Primary Aim #3 and Secondary Aim #1, will then be estimated considering stress as a separate possible concurrent predictor. Interactions between racial group and stress will be considered to investigate possible effect modification due to race.

### **1.6.7 Secondary Aim #3**

Explore the roles of dietary intake and physical activity as potential mediators of weight maintenance.

*Analysis.* Path analysis will be used to determine the roles of dietary intake and physical activity as possible mediators of the relationship between weight maintenance and the potential predictor variables (self-efficacy, low-fat diet experiences, barriers to healthy eating, social support, stress). Because the sample size is fairly small for path analysis and the recommendation of 30 participants per independent variable cannot be met (Munro, 2005), only an exploration of these concepts will be undertaken. In order to examine mediation, models analyzing both the direct effect of each of the predictors on weight maintenance and their indirect effects through dietary intake (fat gram and calorie intake) and physical activity will be fitted. According to Baron and Kenny (1986), three regression equations will be estimated for each predictor: 1) regressing the dependent variable on the predictor, 2) regressing the mediator on the predictor, and 3) regressing the dependent variable on both the predictor and the mediator concurrently (Baron & Kenny, 1986). Paths with large standardized values between the predictor and mediator (dietary intake or physical activity) and between the mediator and weight maintenance will indicate full mediating effect where the direct effect between the predictor and weight maintenance is getting smaller in magnitude. The Sobel test will be used to determine if the effect of the predictor on weight maintenance is significantly reduced when the mediator is included in the model (Sobel, 1982). The estimation of effect sizes using standardized path coefficients will be emphasized rather than the strict testing of hypothesized relationships. Given the small to moderate sample size, bootstrapping will also be considered.



### 1.6.8 Effect Size Estimation and Power

Effect sizes are rarely reported in the weight management literature; however, medium effect sizes for behavioral weight-loss treatment, e.g., .30 and .50, have been reported for weight change in weight-loss and weight-maintenance studies (Leibbrand & Fichter, 2002; Wing, Jeffery, Hellerstedt, & Burton, 1996). Because sample size is fixed, and a total of 119 participants have been recruited for the dissertation study (81 non-minorities and 36 minorities), estimates of effect sizes will be presented based upon pilot analyses from the maintenance period of PREFER, 12 to 18 months. The mean percent weight change (*SD*) for the minority group was +3.7 (3.9)%; the mean percent weight change (*SD*) for the non-minority group was +3.3 (4.1)% in the pilot analysis. For the continuous outcome variable in primary aim #1, in order to achieve 80% power with group sample sizes of 83 white participants and 27 black participants given the existing group standard deviations, a 2.2% difference in mean percent weight change between racial groups would be needed to reject the null hypothesis of no difference in percent weight change between groups, with a significance level of .05 using a two-sided two-sample *t*-test. This difference would result in an effect size of  $d = .549$ , a medium-size effect; the effect size present in the pilot analysis based on a mean difference of .4% is  $d = .10$ , a small effect size (Cohen, 1988).

In primary aim #1 for the categorical variable successful/unsuccessful weight maintenance (defined as  $\leq 10\%$  regain and  $> 10\%$  regain, respectively) the pilot analysis revealed the proportions of minorities and non-minorities regaining  $\leq 10\%$  to be the same. Therefore, proportions were projected based upon the prevalence of obesity for non-Hispanic Blacks and non-Hispanic Whites in 2003-2004, 45% and 31%, respectively (Ogden et al., 2006). Group sample sizes of 83 for the non-minorities and 36 for the minorities achieve 80% power to

detect a difference between the group proportions of .256. The proportion in the minority group is assumed to be .45 under the null hypothesis and .194 under the alternative hypothesis. The test statistic used is the two-sided Likelihood Ratio test at a significance level of .05. The estimated effect size for the 2x2 Chi-square test statistic of 1.892 with a sample size of 119 is  $\Phi = .126$ , a small effect (Rosenthal, 1984).

Primary aim #2 utilizes descriptive statistics only; therefore, no estimations of power or effect size were performed for this aim. For the total sample and each racial group, interval estimates (95% confidence interval) will be computed.

For primary aim #3, using hierarchical multiple regression to examine the influence of predictors on percent weight change, the first model considered only the behavioral variables (barriers to healthy eating, low-fat diet experiences, self-efficacy) as predictors of percent weight change. Based on the pilot analysis from the PREFER data where no potential sociodemographic covariates were identified, an  $R^2$  of .05 was found for the three behavioral predictors. A sample size of 119 achieves 80% power to detect an  $R^2$  of .087 attributed to 3 independent variables using an  $F$ -test with a significance level of .05, which equates to an effect size of  $f^2 = .095$ , a small effect size for social science research (Cohen, 1988). A sample size of 119 achieves 80% power to detect an incremental  $R^2$  of .06 attributed to racial group after adjusting for the 3 behavioral variables with an  $R^2$  of .05. The  $R^2$  change from model 1 with only the 3 behavioral predictors to model 2 with racial group added in the second block was .003, representing a very small effect size for racial group.

Also for primary aim #3, to examine the binary outcome of  $\leq 10\%$  regain or  $> 10\%$  regain, a logistic regression of weight regain on the binary race variable with a sample size of 119 (of which 70% are non-minorities and 30% are minorities) achieves 80% power at .05

significance level to detect a change in probability from the baseline value of .69 to .41. This change represents an odds ratio (effect size) of .31. An adjustment was made since a logistic regression of the race variable on the other behavioral variables in the logistic regression resulted in an  $R^2$  of .044 (Cox and Snell). This odds ratio suggests that the likelihood of successful weight maintenance for minorities is 0.3 times the likelihood of successful weight maintenance for non-minorities. In other words, minorities are 1.3 times more likely to be unsuccessful at weight maintenance compared to non-minorities according to projections from the statistics regarding obesity for Blacks and Whites in 2003-2004.

Stress and social support will be tested in separate models for secondary aims 1 and 2. A sample size of 119 achieves 80% power to detect an  $R^2$  of .06 attributed to one predictor using an F-test with a significance level of .05. When race is added to the second blocks of the separate models after controlling for the effect of stress or social support in the first block, a sample size of 119 achieves 80% power to detect an  $R^2$  of .06. This is a small effect size of  $f^2 = .064$  (Cohen, 1988).

In examining effect sizes for secondary aim 3 which explores the mediating effects of dietary intake (fat grams and calories) and physical activity on predictors of weight maintenance (self-efficacy, barriers to healthy eating, low-fat diet experiences, social support), pilot analyses of the PREFER data revealed that the association of self-efficacy with weight change was influenced by fat gram intake, calorie intake, and physical activity. Estimated effect sizes for these mediator variables, reflected in the change in  $R^2$ , was .014, .001, and .002 for fat gram intake, calorie intake, and physical activity, respectively; each potential mediator was added to the second block in separate regression models with self-efficacy in the first block predicting weight change, in order to determine an estimated effect size for each mediator. The relationship

with other predictor variables (barriers to healthy eating, low-fat diet experiences, social support) and weight change was not influenced by the potential mediators (fat gram intake, calorie intake, and physical activity) in the pilot study, but will still be explored in the dissertation analysis.

## **1.7 STUDY LIMITATIONS**

A limitation of this study is the self-report nature of the data collected, in particular, dietary intake and physical activity. No measure of food intake is ideal (Kipnis et al., 2002; Lissner, 2002), and under-reporting dietary intake is not uncommon (Hill & Davies, 2001; Martin, Su, Jones, Lockwood, Tritchler, & Boyd, 1996), particularly in persons who are overweight or obese (Johansson, Wikman, Ahren, Hallmans, & Johnansson, 2001; Muhlheim, Allison, Heshka, & Heymsfield, 1998). Additionally, over-reporting of physical activity in persons with a higher BMI has been documented (Buchowski, Townsend, Chen, Acra, & Sun, 1999; Irwin, Ainsworth, & Conway, 2001; Jakicic, Polley, & Wing, 1998; Walsh, Hunter, Sirikul, & Gower, 2004; Washburn, Jacobsen, Sonko, Hill, & Donnelly, 2003), and has been associated with poorer weight-loss outcomes (Jakicic et al., 1998). These limitations are difficult to overcome as a result of the design and financial constraints of the dissertation study. Because of the ancillary nature of the study, the measurement tools were based upon the measures used in the PREFER study, with the exception of the 24-hour dietary recalls.

The PREFER trial used the 3-Day Food Diary, which included nonconsecutive days (one non-working day and two work days) that are representative of their typical eating habits. The PI of the PREFER study conducted an ancillary study of her own at the same time as data collection for the first cohort of the dissertation study and decided to switch to 24-hour dietary recalls for

assessment of food intake as the recalls are considered more accurate. Therefore, 24-hour dietary recalls were continued for the second and third cohorts of the dissertation study to maintain data consistency. Both of these measures will be analyzed for total caloric and fat gram intake using the NDSR software, but there might be some difference in self-reported food intake because the 3-Day Food Diary is a planned recording of foods eaten and could influence actual eating; the 24-hour dietary recall assessment is unannounced and collects past behavior data. The measurement of dietary intake is unfortunately limited to self-report, as no objective measures of consumed foods are currently available. A possible method to increase the accuracy of the data would be to collect several measures of dietary intake and compare the similarity of the data. This technique would unfortunately only present a measure of reliability in terms of what the participant reported and would increase subject burden without increasing the validity of the assessment. The “gold standard” for measuring energy expenditure and physical activity in free-living individuals is the use of doubly labeled water (Ravussin, Harper, Rising, & Bogardus, 1991; Schoeller & van Santen, 1982; Schoeller & Webb, 1984). This technique is based on the difference in the elimination of deuterium ( $^2\text{H}$ ) and  $^{18}\text{oxygen}$  ( $^{18}\text{O}$ , eliminated as water and carbon dioxide) from body water after an oral dose of the two stable isotopes; energy expenditure is calculated from the production of carbon dioxide using equations for indirect calorimetry (Mann et al., 2007; Tataranni & Ravussin, 2002). However, it is very expensive, costs more than \$1000 to assess a 70 kg person (Speakman, 1997), and was not used in the PREFER study.

A possible limitation of the dissertation study is a potential differential recruitment of participants who have done well in terms of maintaining their weight since the completion of the PREFER study. This selection bias is a pitfall of long-term weight-loss studies (Cox et al., 2007;

Heshka et al., 2003; Phelan, Hill, Lang, Dibelllo, & Wing, 2003), but every attempt will be made to encourage all eligible participants to return for the dissertation study no matter what they currently weigh. The recruitment letter stresses that information is needed from participants who were not as successful in their maintenance efforts as well from those who were.

## **1.8 PROTECTION OF RESEARCH PARTICIPANTS**

The researcher will seek approval for the research through the University of Pittsburgh IRB. The IRB will approve all aspects of the study before any research activities are initiated. Potential risks to the research participants are minimal and include possible embarrassment if they have regained weight; this risk will be minimized as much as possible by voicing acceptance of the participant and emphasizing that this study is to learn how to help individuals with maintenance of lost weight. All weights will be obtained in a private setting. The potential risk of breach of confidentiality is reduced by keeping identifying personal information in a separate, locked filing cabinet from the research data. Data will be de-identified, assigned an identification number, and kept in another locked filing cabinet.

The population of the dissertation study is based on the demographic characteristics of the PREFER study. Characteristics of the sample include male and female (87.4%) adults age 18-55 years old at enrollment of the PREFER study and a 29.5% representation of minorities, which is characteristic of the Pittsburgh regional area. Because the primary interest is in exploring racial differences in weight maintenance, recruitment activities will make every effort to maintain this proportion. Dr. Stephen Thomas, Director of the Center for Minority Health, is a consultant to the dissertation study and will provide assistance in recruiting PREFER study

minority persons to participate. Children under 18 years of age were not included in the PREFER study due to the need for parental involvement. Adults beyond 55 years old were not included in the PREFER study to reduce the possibility of co-morbid conditions that might prohibit participation in physical activity.

## 1.9 PUBLICATIONS

### *Refereed Articles (\*databased)*

- \*Burke, L.E., **Warziski, M.**, Starrett, T., Choo, J., Music, E., Sereika, S., Stark, S. & Seveck, M.A. (2005). Self-monitoring dietary intake: Current and future practices. *Journal of Renal Nutrition*, 15(3), 281-290.
- \*Burke, L.E., Choo, J., Music, E., **Warziski, M.**, Styn, M.A., Kim, Y., & Seveck, M.A. (2006). PREFER study: A randomized clinical trial testing treatment preference and two dietary options in behavioral weight management– Rationale, design and baseline characteristics. *Contemporary Clinical Trials*, 27, 34-48.
- \*Burke, L.E., Sereika, S., Choo, J., **Warziski, M.**, Music, E., Styn, M.A., Novak, J., & Stone, A. (2006). Ancillary study to the PREFER trial: A descriptive study of participants’ patterns of self-monitoring – Rationale, design and preliminary results. *Contemporary Clinical Trials*, 27, 23-33.
- \*Burke, L.E., Styn, M.A., Music, E., **Warziski, M.**, Aaron, D., Choo, J. & Sereika, S. (2006). A randomized clinical trial testing treatment preference and two dietary options in behavioral weight management: Preliminary results of the impact of diet at 6 months-- PREFER study. *Obesity*, 14(11), 2007-2017.

- \***Warziski, M.**, Sereika, S.M., Styn, M.A., Music, E., Burke, L.E. (2007). Changes in self-efficacy and dietary adherence: The impact on weight loss in the PREFER study. *Journal of Behavioral Medicine*, 31, 81-92.
- \*Burke, L.E., **Warziski, M.**, Styn, M.A., Music, E., Hudson, A.G., & Sereika, S.M. (2008). A randomized clinical trial of a standard versus vegetarian diet for weight loss: The impact of treatment preference. *International Journal of Obesity*, 32, 166-176.
- \*Burke, L.E., Hudson, A.G., **Warziski, M.**, Styn, M.A., Music, E., Elci, O.U., Sereika, S.M. (2007). Effects of a vegetarian diet and treatment preference on biological and dietary variables in overweight and obese adults: A randomized clinical trial. *American Journal of Clinical Nutrition*, 86, 588-596.
- \* Burke, L.E., Sereika, S.M., Music, E., **Warziski, M.**, Styn, M.A., Stone, A. (2008). Using instrumented paper diaries to document self-monitoring patterns in weight loss. *Contemporary Clinical Trials*, 29, 182-193.

#### *Book Chapters*

- Warziski, M.**, Choo, J., Novak, J., & Burke, L.E. (2008). Obesity. In D. Moser & B. Riegel (Eds.), *Cardiac nursing: A companion to Braunwald's heart disease* (pp. 446-484). St. Louis: Saunders.

#### *Published Abstracts*

- Burke, L.E., Sereika, S., Choo, J., **Warziski, M.**, Novak, J., Music, E. & Cartwright, M. (2005). Self-monitoring among subjects in a weight loss study. *European Journal of Cardiovascular Nursing*, 4(1), 64-65.
- Burke, L.E., Choo, J., Music, E., Cartwright, M., **Warziski, M.**, & Kim, Y. (2005). Does



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## **1.10 RESEARCH PARTICIPANT RISK AND PROTECTION**

### *Human Participants*

*Description.* The population of the dissertation study is based on the demographic characteristics of the PREFER study. Characteristics of the sample population: male and female adults and 18-55 years old at enrollment of the PREFER study, including 87.4% females; this proportion will likely be maintained. The PREFER study had a representation of 29.5% minorities, and recruitment activities will make every effort to maintain this proportion. Dr. Stephen Thomas, Director of the Center for Minority Health, is a consultant to the dissertation study and will provide assistance in the recruitment of PREFER study minority participants. The eligibility criteria are dictated by the inclusion criteria of the PREFER study; participants were 18-55 years old at enrollment of the PREFER study, agreeable to randomization to their treatment preference or not and one of the two dietary plans, had a BMI between 27 and 43 kg/m<sup>2</sup>, inclusively, and had adequately completed a 5-day food intake diary. Females of childbearing potential will be included in this study since there is no intervention is being used. All 132 participants from the

PREFER study who complete the final assessment are eligible for the dissertation study, and no one will be excluded based on current weight, age, gender, or ethnicity.

According to the inclusion criteria of the PREFER, children under the age of 18 and adults older than 55 were not eligible to participate, and thus will not be included in the dissertation study. Children under 18 years of age were not included in the PREFER study because of the need for comprehension of the two dietary choices and identification of a preferred choice. Furthermore, the adoption of a reduced-calorie and reduced-fat eating plan or a vegetarian eating plan necessitates significant changes in meal selection and preparation, which could not be accomplished without parental supervision. The PREFER study intervention protocol did not allow for parental involvement. Those older than 55 were excluded from the PREFER study to reduce the chance of co-occurring medical conditions that might not allow for participation in physical activity.

*Sources of data.* Existing data from the completion of the PREFER study— weight, 3-Day Food Diary, Paffenbarger Activity Questionnaire, Experiences Associated with Following a Low-fat Diet Scale, Barriers to Healthy Eating Scale, and Weight Efficacy Lifestyle Questionnaire— will be used in the dissertation study. These data, which have previously been de-identified, exist in the secure database of the PREFER study. Data not collected as part of the PREFER trial but used in the dissertation study include the Self-Efficacy for Exercise Scale, Behavioral Strategy Survey, and 24-hour dietary recalls. All new data and documents will be de-identified and maintained so that no linkage can be made to the individual enrolled in the study. All data with only identification numbers will be stored in a locked filing cabinet, and all records connecting names to ID numbers will be stored in a separate locked filing cabinet. Dietary recall data are de-identified and stored in a secure database. All data will be compliant with the

guidelines of the Complete Health Insurance Portability and Accountability Act (HIPPA) of 1996, and no data will be able to be linked to the individual participant.

*Recruitment procedures.* Eligible participants will receive a letter from the PI of the PREFER study and the PI of the dissertation study, and a consent form approximately 16 months post-completion of the PREFER study. The letter will explain the interest in exploring the factors involved in weight maintenance and ask that they return for one assessment. To encourage participants who may be reluctant to respond because they have gained weight, the letter will stress the interest in examining issues related to weight management regardless of current weight. See Appendix E for letter. During the phone call, the study will be explained to the participant, and the person will be asked if he/she has any questions about the consent form. Consent forms will be returned by mail and participants will be mailed the questionnaires and contacted to schedule an appointment for their weight assessment once the consent form is received; a copy of the consent form will be given to the participant at their appointment. Written informed consent will be obtained per IRB protocol to allow the use of secondary data from the PREFER study as well as to collect the additional measures described above. The PREFER study had a 76% ( $N = 132$ ) retention of participants at the final assessment. Due to the high retention of the PREFER study, the projected loss of participants for the dissertation study is an additional 10% beyond that of the PREFER study. Based on PREFER study retention and subsequent attrition at 18-month follow-up, a projected recruitment of 119 participants is expected, maintaining the 29.5% minority composition (84 non-minorities, 35 minorities).

*Potential risks.* There are minimal risks involved in participation in the proposed ancillary study. No intervention with any inherent risks is being conducted and no other potential physical, psychological, social, or legal risks are anticipated. Participants may feel embarrassed

if they have regained weight. The likelihood of this occurrence is unknown, but will be minimized by the fact that the PI is known to the participants and assisted with the weigh-ins during the intervention. Any participant discomfort issues will be directed to Dr. Lora Burke and Dr. Lin Ewing. Dr. Ewing is a clinical psychologist and will provide direct guidance in dealing with any participant distress related to weight regain. The potential risk for loss of confidentiality also exists; however, the likelihood of this occurring is minimal because the PI will be the only one accessing the data, and all data will be de-identified and secured as described under Sources of Data.

*Procedures to minimize risks.* The risk of embarrassment will be minimized as much as possible by verbalizing acceptance of the participant at his/her current weight and emphasizing that we are trying to learn how to help individuals maintain their weight loss. All weights will be obtained in a private area. Persons with a serious illness or under treatment for a psychological disorder will have been previously excluded from the PREFER study and therefore not eligible for the dissertation study. If a participant has developed an illness requiring psychiatric treatment in the 18-month interim, this person will be excluded for the protection of the participant. The risk for loss of confidentiality will be minimized by de-identifying data and using the procedures discussed under Sources of Data. The PI will meet bi-weekly with the PI of PREFER to review accrual of participants and data quality to make certain that there are no changes in the risk/benefit ratio. The risk for the dissertation study is significantly less than the PREFER study since there are no interventions and no invasive procedures e.g. blood draws. The most significant risk is the potential for participant discomfort due to weight regain. Any questions or concerns related to participant safety or comfort will be directed to Dr. Lora Burke and Dr. Lin Ewing. Because Dr. Ewing is a clinical psychologist, she will provide direct guidance in

handling any participant distress. The PI will immediately report any adverse events to the University of Pittsburgh IRB and will notify the NIH and IRB of any necessary modifications to this protocol. No protocol modification will be instituted without IRB approval.

*Cost-to-benefit ratio.* While no direct benefit to the participant may result from taking part in the dissertation study, there is a hope that future participants will benefit from the information acquired, which will assist in the generation and implementation of behavioral interventions to improve long-term weight maintenance with strategies tailored to possible racial differences.

*Research Study Costs:* All research costs will be covered by the dissertation study.

*Research Study Payments:* Participants will be compensated for their time with a \$25.00 gift certificate to Giant Eagle grocery stores.

*Vertebrae animals:* None.

## **2.0 SUMMARY OF DISSERTATION STUDY**

The dissertation project examined weight maintenance after a behavioral weight loss trial, PREFER, and explored whether differences existed between black and white participants in percent weight change and successful weight maintenance 18 months after the trial. In the original proposal, successful weight maintenance was defined as  $\leq 10\%$  weight regain. However, after examining the data, this cut point would have resulted in a very small cell size ( $< 5$ ) for the black participants in the unsuccessful group, making the use of the planned logistic regression analysis problematic as the model could become unstable and result in inappropriate maximum likelihood estimates (Stokes, Davis, & Koch, 2001). Although a procedure is available in the SAS statistical software package (SAS Institute Inc., Cary, NC, USA) to handle logistic regression with small cell counts, i.e. PROC LOGISTIC EXACT, the existing literature on weight maintenance often uses either a 5% or 10% weight change cut point to define successful weight maintenance after loss (Field, Wing, Manson, Spiegelman, & Willett, 2001; Gosselin & Cote, 2001; Lowe, Miller-Kovach, & Phelan, 2001; Stevens, Truesdale, McClain, & Cai, 2006), and in fact, more recent publications use the 5% weight gain marker (Befort, Stewart, Smith, Gibson, Sullivan et al., 2007; Cox, Malpede, Desmond, Faulk, Myer et al., 2007; Greene, Malpede, Henson, Hubbert, Heimbürger et al., 2006). Therefore, after consultation with Drs. Burke and Sereika, the decision was made to redefine successful weight maintenance as  $\leq 5\%$



regain. The findings from the dissertation study are organized and presented in three manuscripts as described below.

The first manuscript, An Exploration of Racial Differences and Psychosocial Correlates of Weight Maintenance after a Behavioral Weight Loss Trial, addresses the following specific aims:

Primary aim 1. Investigate if there are differences between black and white persons in the percentage of weight change, as well as successful weight maintenance defined as  $\leq 5\%$  weight regain, at 18 months post-completion of the PREFER study.

Primary aim 3. Examine the influence of possible predictors (self-efficacy, experiences in following a low-fat diet, barriers to healthy eating) on percentage of weight change and successful weight maintenance and whether race moderates the relationship between identified predictors and weight maintenance.

Secondary aim 1. Describe the impact of social support on weight maintenance for black and white persons.

Secondary aim 2. Describe the impact of stress on weight maintenance for black and white persons.

In brief, there was no significant difference in percent weight change ( $p = .55$ ) or unsuccessful weight maintenance ( $p = .53$ ) between the black and white participants with both groups gaining approximately 5% of their weight. Race did not moderate the relationship between the predictors and weight change or unsuccessful weight maintenance,  $ps > .10$ . An increase in barriers to healthy eating and the effect of a stressful life event on eating were significantly associated with weight regain and unsuccessful weight maintenance,  $ps < .04$ . Although a difference in weight change between black and white participants after the weight

loss trial was not supported, these findings indicate the need to develop novel strategies to assist all individuals overcome barriers to following a healthful dietary plan and deal with stressful life events.

The findings for the second primary aim are described in the second manuscript, Use of Behavioral Strategies for Weight Maintenance 18 Months after a Behavioral Weight Loss.

Primary aim 2. Describe the behavioral strategies utilized by black and white persons for weight maintenance.

This analysis examined the percentage of the time participants used behavioral weight management strategies they learned during the weight loss trial. Whether or not a difference existed in strategy use between black and white participants as well as between successful and unsuccessful weight maintainers was also explored. Only a quarter of the behavioral strategies were used for more than half the time. For all participants, reading food labels while grocery shopping was the strategy used for the greatest proportion of the time. Two differences in strategy use were found between the black and white participants; black participants used recipe modification and portion-control methods for significantly less time than white participants,  $ps < .04$ . Successful and unsuccessful participants did not differ in strategy use. Because individuals who are successful at weight maintenance report using a number of behavioral strategies to manage their weight, (Befort et al., 2007; Kitsantas, 2000; Leser, Yanovski, & Yanovski, 2002; McGuire, Wing, Klem, Seagle, & Hill, 1998; Wing & Hill, 2001), methods to promote the continuation of behavioral strategies long-term are needed. A few differences existed in strategy use between racial groups supporting the incorporation of culturally-tailored intervention techniques in weight management programs to meet the needs of these individuals.

The third manuscript, Dietary Intake and Physical Activity as Potential Mediators of the Relationship between Psychosocial Variables and Weight Maintenance after a Weight Loss Trial, addresses the third secondary aim:

Secondary aim 3. Explore the roles of dietary intake and physical activity as potential mediators of the relationships between weight maintenance and 1) barriers to healthy eating, 2) experiences in following a low-fat diet, 3) self-efficacy, 4) social support, and 5) stress.

Calorie and fat gram intake and physical activity did not mediate the relationship between the psychosocial variables and weight maintenance. Increases in the BHE scale, decreases in the ELF scale, and decreases in the WEL scale as well as a greater effect of a stressful life event on eating were found to significantly predict weight regain in univariate analyses,  $ps < .03$ . An increase in barriers also predicted increased fat gram intake,  $p = .048$ . Several focus areas for weight maintenance interventions are identified through these findings, e.g., helping individuals learn to decrease barriers to healthy eating, increase positive experiences while following a low-fat dietary lifestyle, augment eating-related self-efficacy, and appropriately deal with stressful life events.

This research project has several strengths and some limitations. These are addressed in greater detail in the manuscripts but are highlighted here. The strengths of this investigation include that it was a long-term assessment of weight maintenance and adds to the limited findings regarding long-term weight maintenance after a behavioral weight loss trial. This project explored maintenance among black individuals, and there is little information about weight maintenance in this racial group. The study used an objective assessment of weight and a large proportion of participants who completed the weight loss trial returned to participate, reducing the possibility of biased findings resulting from only individuals who maintained their

weight participating in the follow-up study. The sample was originally recruited using multiple sources, e.g. mass mailings, posted advertisements, automated telephone announcement system, and participants were from a diverse community, supporting the generalizability of the results. Limitations include a restriction of the sample selection to those who took part in the weight loss trial, thereby limiting the demographic characteristics of the participants and the representation of black participants. The sample size of 26 black individuals (22% of the sample) might not be deemed large enough to make conclusions about weight maintenance in this racial group. The small percentage of men would suggest that the results could be generalized only to women. The socioeconomic status of the sample was somewhat higher than average for Allegheny County and Pennsylvania with more than half of the white and black participants reporting an annual household income of at least \$50,000, and the mean level of education for the entire group was also relatively high at over 15 years of formal education. These factors might limit the generalizability of the findings to individuals at this socioeconomic level. Self-reported measurement of variables also introduces possible recall bias and social desirability when completing questionnaires. In particular, the dietary and physical activity assessments are subject to underreporting and over reporting, respectively. Manuscript three addresses this limitation further.

Implications for future studies are also discussed in the manuscripts. These include research that focuses on the most appropriate strategies for reducing participants' barriers to following a healthy eating plan and assisting individuals to cope with stressful life events in order to promote weight loss maintenance. Further investigations are needed to determine how to best encourage people to continue to use behavioral strategies for controlling weight. An exploration is warranted regarding how individuals choose or do not choose to utilize particular

behavior strategies for weight management. Future research needs to explore racial differences in the ability and interest of black persons in modifying recipes and using portion control methods. Additional studies should examine incorporating specific instructions on how to prepare more healthful ethnic dishes and ethnic-style meals (Gans, Kumanyika, Lovell, Risica, Goldman et al., 2003; Kumanyika, Shults, Fassbender, Whitt, Brake et al., 2005).

### **3.0 LITERATURE REVIEW MANUSCRIPT**

#### Randomized Clinical Trials of Weight-loss Maintenance: A Review

### **3.1 ABSTRACT**

The problem of overweight and obesity has reached epidemic proportions in the U.S. and globally, and the high prevalence is due in part to the recidivism associated with weight-loss treatment. Approximately one third of lost weight is often regained in the first year after treatment and, at times, continues. Because a plethora of co-morbid diseases are associated with obesity, in particular, cardiovascular disease, hypertension and hyperlipidemia, clinicians and researchers have attempted to find useful strategies for maintaining weight loss. This review presents the findings from 42 randomized clinical trials of weight-loss maintenance from 1984 through 2007 utilizing interventions that include 1) the Internet, 2) strategies after a very-low-calorie diet, 3) pharmacotherapy, 4) behavioral strategies, 5) physical activity, and 6) alternative strategies. The results of the reviewed trials revealed that treatment with orlistat or sibutramine combined with dietary modification, caffeine or protein supplementation, consuming a diet lower in fat, adherence to physical activity routines, prolonged contact with participants, problem-solving therapy, and the alternative treatment acupuncture were efficacious in reducing weight regain after weight-loss treatment. The limitations of some studies may reduce the robustness of

their findings, and future studies are necessary to replicate and support these results so that individuals are able to maintain weight loss and retain the health benefits associated with a lower weight.

### **3.2 INTRODUCTION**

Overweight and obesity are worldwide, chronic health problems that are associated with heart disease and stroke (Eckel, York, Rossner, Hubbard, Caterson et al., 2004), and 66.3% of the U.S. population falls into one of these two weight categories (Centers for Disease Control and Prevention, 2007). Overweight and obesity are measured by body mass index (BMI), i.e., weight in kilograms divided by height in meters squared. Overweight is defined as a BMI between 25.0 kg/m<sup>2</sup> and 29.9 kg/m<sup>2</sup> and obesity as a BMI  $\geq$  30 kg/m<sup>2</sup>. Obesity is categorized further by obesity I (BMI between 30.0 kg/m<sup>2</sup> and 34.9 kg/m<sup>2</sup>), obesity II (35.0 kg/m<sup>2</sup> to 39.9 kg/m<sup>2</sup>), and a BMI greater than 40.0 kg/m<sup>2</sup> is obesity III or extreme obesity (National Heart Lung and Blood Institute Obesity Education Initiative Expert Panel on the Identification Evaluation and Treatment of Overweight and Obesity, 1998). With increasing levels of BMI, the associated level of risk for cardiovascular disease (CVD) and development of type 2 diabetes increases; a BMI  $\geq$  30 kg/m<sup>2</sup> is an independent risk factor for CVD (Klein, Burke, Bray, Blair, Allison et al., 2004). Moreover, central adiposity, mainly visceral fat, is a strong risk factor for hypertension, dyslipidemia, and insulin resistance (Adams & Murphy, 2000).

The usual course of weight-loss therapy shows that weight is lost quickly at first, and the point of greatest loss occurs 6 months after beginning treatment; then weight is slowly regained until weight returns near the original level (Jeffery, Drewnowski, Epstein, Stunkard, Wilson et

al., 2000). Often, 30-35% of the weight a person loses is regained during the first year after treatment (Wadden, Butryn, & Byrne, 2004), and weight gain frequently persists with an average loss of about 1.8 kg remaining at four years after treatment (Perri & Foreyt, 2004). Approximately 20% of individuals could be considered successful when *successful* weight-loss maintenance is defined as intentionally losing at least 10% of one's weight and maintaining that loss for a minimum of one year (Wing & Hill, 2001). While weight-loss treatment programs have succeeded at assisting people to lose weight, helping to maintain the loss has remained an elusive endeavor despite the use of multiple behavioral change strategies.

Investigations into how to best promote weight-loss maintenance have examined several strategies e.g., ongoing therapist contact, training in relapse prevention, problem-solving therapy, providing pre-packaged foods, incorporating support from peers, and including multifaceted programs after weight-loss treatment (Perri & Corsica, 2002). Relapse prevention training involves instruction in recognizing high-risk circumstances for potential lapses, practicing dealing with high-risk circumstances like eating at parties or restaurants, and restructuring negative thoughts to cope with guilt related to a lapse or failure (Marlatt & Gordon, 1980). The application of problem solving involves a 5-step process that includes having the individual identify the problem, formulate alternative solutions, make decisions, and test and evaluate those decisions until the problem is resolved (D'Zurilla & Goldfried, 1971). Yet even with interventions targeting relapse, the issue of poor maintenance of lost weight remains, causing some to question whether maintenance programs are helpful or only postpone weight regain at an added cost (Mustajoki & Pekkarinen, 1999).

Weight loss and maintenance can improve or even prevent risk factors for CVD and the development of co-morbidities related to obesity (Klein et al., 2004). Modest weight loss (5-10%



of initial weight) is associated with an improvement in several established risk factors for CVD e.g., hypertension (Masuo, Mikami, Ogihara, & Tuck, 2001; Mertens & Van Gaal, 2000; Neter, Stam, Kok, Grobbee, & Geleijnse, 2003), dyslipidemia (Klein et al., 2004), reduced incidence of type 2 diabetes mellitus (Knowler, Barrett-Connor, Fowler, Hamman, Lachin et al., 2002; Lindstrom, Louheranta, Mannelin, Rastas, Salminen et al., 2003; Pi-Sunyer, 2007), as well as improvement in control of diabetes (The Look AHEAD Research Group, 2007). A meta-analysis of 25 randomized controlled trials examining blood pressure found that a weight loss of 5.1 kg resulted in a 4.44 mm Hg reduction in systolic blood pressure and a 3.57 mm Hg decrease in diastolic blood pressure; significantly greater reductions in blood pressure were seen when the average weight loss was greater than 5 kg (Neter et al., 2003). However, the positive effects of weight loss on CVD risk factors do not remain unless weight loss is maintained. While serum triglyceride and LDL cholesterol levels typically decrease during the first two months of weight loss, a weight regain causes lipids to return to former levels (Wadden, Anderson, & Foster, 1999), making the prevention of weight regain imperative.

The National Weight Control Registry is an ongoing registry of individuals who have been successful at losing and maintaining a minimum of 13.6 kg for at least 1 year (Klem, Wing, McGuire, Seagle, & Hill, 1997). Many descriptive studies of this cohort have reported on behavioral strategies used by these successful individuals, including increasing physical activity, consuming a low-fat diet, regularly self-monitoring foods eaten and body weight (Wing & Hill, 2001), restricting the variety of foods eaten (Raynor, Jeffery, Phelan, Hill, & Wing, 2005), consuming a consistent weekly diet (Gorin, Phelan, Wing, & Hill, 2004), eating breakfast (Wyatt, Grunwald, Mosca, Klem, Wing et al., 2002), and limiting the amount of time spent watching television (Raynor, Phelan, Hill, & Wing, 2006). The generalizability of this

information is limited, however, by the descriptive nature of the studies and the demographics of the sample, which is 77% female and 95% Caucasian with 82% having a college education (Wing & Phelan, 2005). As a result of the rigorous methodology, the most robust empirical evidence comes from the randomized clinical trial (RCT), and the RCT is considered the second strongest level of evidence, after meta-analyses of controlled trials, in the evidence hierarchy for Evidence-Based Practice (Stetler, Brunell, Giuliano, Morse, Prince, & Newell-Stokes, 1998). Therefore, the purpose of this paper is to summarize for clinicians and researchers the strategies from RCT research of weight-loss maintenance that have been efficacious in assisting individuals in maintaining their weight after weight loss.

### **3.3 METHODS**

In order to assess what methods have been reported as beneficial for maintaining weight loss, the existing literature was searched electronically using the databases of Medline, Allied and Complementary Medicine (AMED), Cumulative Index to Nursing & Allied Health Literature (CINAHL), and PsycINFO using the keywords *weight loss maintenance*, *weight loss*, *obesity*, *overweight*, and *long-term weight loss*. In addition, a hand search of pertinent articles was conducted for other relevant articles. The criteria for inclusion in the review were 1) a randomized clinical trial of a weight-loss maintenance intervention after an initial weight loss, 2) adult population ( $\geq 18$  years of age, 1 trial  $> 17$  years old), and 3) English language. In order to isolate the specific effect on weight-loss maintenance, only trials that used a true experimental design and randomly assigned participants to an intervention for maintenance were included. Thus, weight-loss trials with a maintenance phase that did not randomly assign participants to the

maintenance intervention were excluded. Because some early papers were identified as important in the development of knowledge related to weight-loss maintenance, papers from 1984 to 2007 were included. Subsequent articles reporting on the same intervention study were excluded. Four-hundred and eighty-two relevant articles were initially identified. Most were excluded because they did not report on a randomized clinical trial of weight-loss maintenance ( $n = 314$ ). Others were excluded because the main outcome was not weight-loss maintenance, e.g. short-term weight loss, metabolic syndrome, diabetes ( $n = 126$ ). Thus, 42 articles on weight-loss maintenance were included in the review. Findings from studies were organized according to the types of interventions used for weight-loss maintenance, and six categories of studies were found, those using 1) the Internet, 2) maintenance strategies after a very-low-calorie diet, 3) pharmacotherapy, 4) behavior therapy, 5) physical activity, and 6) alternative therapies. Most trials required that participants lost at least 5% of initial body weight during the weight-loss period before being randomized to the weight-loss maintenance intervention, although one medication trial required only a 2% weight loss (Wirth & Krause, 2001). Measures of the principal outcome of interest, weight change (continued loss, maintenance, or regain), were expressed in 1) absolute weight change (kg or lbs) or percentage of weight loss from the completion of the weight-loss period to the completion of the maintenance intervention or 2) from prior to weight-loss treatment to the end of maintenance or follow up based on the reporting of the article. In order to determine the magnitude of the treatment effect for each study, effect sizes (ES) were calculated by converting the p-value to a z-score and using the equation,  $ES = \Phi = Z / n^{1/2}$ , unless a p-value was not reported, then the Cohen's  $d$  was determined from the difference between the two group means divided by the pooled standard deviation for those means (Cohen, 1988).

### 3.4 FINDINGS

#### 3.4.1 Internet

Technological advances have permitted the use of less traditional methods for encouraging weight-loss maintenance. The four randomized trials listed in Table 3.1 used the Internet as an innovative strategy to assist participants in sustaining their lost weight. In general, these studies compared the use of an Internet-based weight-loss maintenance intervention with online chat room sessions to in-person group behavioral therapy sessions after a behavioral weight-loss trial (Harvey-Berino, Pintauro, Buzzell, & Gold, 2004; Harvey-Berino, Pintauro, Buzzell, DiGiulio, Casey Gold et al., 2002a; Harvey-Berino, Pintauro, & Gold, 2002b; Wing, Tate, Gorin, Raynor, & Fava, 2006). Results were mixed, and two studies found no difference in weight-loss maintenance between groups, suggesting that a behavioral intervention conducted over the Internet may be as effective as in-person without the higher cost of conducting face-to-face treatment (Harvey-Berino et al., 2004; Harvey-Berino, Pintauro, & Gold, 2002b). Harvey-Berino et al. (2004) found the program via the Internet resulted in long-term weight losses similar to in-person programs. In an earlier trial by this group, all persons continued to lose weight during weight maintenance despite no significant differences between groups (Harvey-Berino, Pintauro, & Gold, 2002b). However, a comparison of Internet treatment to minimal and frequent in-person treatment found that the Internet group maintained significantly less weight at the end of the trial than the in-person groups,  $p < .05$ ; weight maintenance differences were observed between the different types of participant contact rather than the different intensities of contact (Harvey-Berino, Pintauro, Buzzell et al., 2002a). Similarly, after controlling for percent weight loss during the weight-loss trial, an Internet chat room intervention was found to be less effective in

preventing weight regain than the in-person, group behavioral treatment,  $p = .02$ ; yet, adherence to the self-regulatory behavior of weighing oneself was significantly related to maintaining weight loss,  $p < .001$  (Wing et al., 2006).

### **3.4.2 Very-Low-Calorie Diet (VLCD)**

Nineteen reviewed studies examined weight-loss maintenance trials after a VLCD and have included additional intervention strategies such as 1) medications, 2) meal replacements, macronutrient and other dietary intervention or supplementation, 3) periodic use of the VLCD or prepackaged foods, and 4) exercise. A VLCD usually provides less than 800 kcal/day in a liquid form, is medically supervised to monitor electrolyte balance, includes vitamin and mineral supplementation and has been shown to produce rapid, substantial weight loss (Wadden & Osei, 2002). However, sizable weight regain after these diets is also typical (Saris, 2001), and they may offer no long-term benefit over traditional reduced-calorie diets of ~1200-1800 kcal/day (Gilden Tsai & Wadden, 2006; Wadden, Foster, & Letizia, 1994). The reviewed studies began with a VLCD for varying lengths of time (4 to 16 weeks) using caloric intakes ranging from 220 to 1000 kcal/day, and then participants were randomized to a weight-loss maintenance intervention. See Table 3.2.

#### *VLCD followed by medications in maintenance*

In seven trials of weight-loss maintenance after a VLCD, four types of medications were administered— orlistat, sibutramine, acarbose, or sertraline. Three studies examined orlistat (Laaksonen, Laitinen, Schonberg, Rissanen, & Niskanen, 2003; LeCheminant, Jacobsen, Hall, & Donnelly, 2005; Richelsen, Tonstad, Rossner, Toubro, Niskanen et al., 2007), a lipase inhibitor

that decreases absorption of dietary fat in the gastrointestinal tract (Drent, Larsson, William-Olsson, Quaade, Czubyko et al., 1995). Two trials investigated sibutramine (Apfelbaum, Vague, Ziegler, Hanotin, Thomas et al., 1999; Mathus-Vliegen, 2005), which suppresses appetite by inhibiting the reuptake of norepinephrine and serotonin (McNeely & Goa, 1998). The effect on weight-loss maintenance of acarbose, an oral medication to treat type 2 diabetes, and sertraline, a serotonin reuptake inhibitor, was evaluated in one study each (Hauner, Petzinna, Sommerauer, & Toplak, 2001; Wadden, Bartlett, Foster, Greenstein, Wingate et al., 1995). Two trials using orlistat versus placebo (Laaksonen et al., 2003; Richelsen et al., 2007) and one examining orlistat versus meal replacements (LeCheminant et al., 2005) found no difference in weight regain between groups at completion of the intervention. Laaksonen and colleagues found that those who lost and maintained a loss of  $\geq 10\%$  regained less weight during weight maintenance than those who lost less (2003). In a 3-year study where participants received orlistat or placebo, the orlistat group maintained 2.4 kg more lost weight than those receiving placebo; 67% in the orlistat group compared to 56% in the placebo group were 5% or more below baseline weight at 3 years,  $p = .037$  (Richelsen et al., 2007). While all three orlistat studies used some form of a reduced-calorie diet for all participants, only the 3-year study resulted in significant differences between groups. Both sibutramine interventions were of a sizable length and found weight-loss maintenance to be superior in the sibutramine groups versus placebo (Apfelbaum et al., 1999; Mathus-Vliegen, 2005), with a greater proportion of the sibutramine group in one trial (Apfelbaum et al., 1999) maintaining a higher percentage of lost weight than the other (Mathus-Vliegen, 2005). Weight loss by VLCD was better sustained with sibutramine and reduced-calorie diet than with placebo and reduced-calorie diet (Mathus-Vliegen, 2005). Apfelbaum et al. (1999) found that those who received sibutramine continued to lose weight in the weight maintenance

period while those who received a placebo regained (Table 3.2). In terms of weight regain, there was no difference between acarbose and placebo, with both groups remaining relatively weight stable and no observed benefit from acarbose (Hauner et al., 2001). Wadden and colleagues found that the sertraline group regained more of their lost weight than placebo,  $p = ns$ , but that both groups maintained more than 8% of their original weight loss (Wadden et al., 1995).

*VLCD followed by a dietary component in maintenance*

Table 3.2 also lists seven trials after a VLCD that evaluated the use of a dietary intervention, macronutrients, and other dietary supplements. Treatments used included an ad lib, high-carbohydrate low-fat diet versus a calorie-restricted diet (Toubro & Astrup, 1997), green tea use (Kovacs, Lejeune, Nijs, & Westerterp-Plantenga, 2004; Westerterp-Plantenga, Lejeune, & Kovacs, 2005), increasing protein intake (Lejeune, Kovacs, & Westerterp-Plantenga, 2005; Westerterp-Plantenga, Lejeune, Nijs, van Ooijen, & Kovacs, 2004), adding fiber (Pasman, Westerterp-Plantenga, Muls, Vansant, van Ree et al., 1997), and supplementing carbohydrate intake (Pasman, Westerterp-Plantenga, & Saris, 1997). One study (Toubro & Astrup, 1997) tested the effect of an ad lib, high-carbohydrate, low-fat diet compared to a reduced-calorie diet (1875 kcal/day) that utilized color-coded cards to represent food groups and calorie content; the ad lib group regained less weight. Consumed calories from fat were higher in the reduced-calorie group compared to the ad-lib group, suggesting that eating a lower-fat diet could be important in weight-loss maintenance (Toubro & Astrup, 1997). The effect of a green tea-caffeine mixture on weight-loss maintenance appears to be contingent upon the individual's baseline level of caffeine intake. For example, Kovacs et al. (2004) found no difference in weight regain between the green tea and placebo groups until the sample was divided into low ( $< 300$  mg) and high ( $> 300$  mg) caffeine consumers for the analysis; the high caffeine consumers regained more weight than the

low caffeine consumers,  $p < .05$ . A later study by the same investigators reported that the percentage of weight regained was significantly less in the group who received the green tea mixture & had consumed low levels of caffeine at baseline,  $p < .01$ , suggesting a possible maximum effect of caffeine on weight management and thermogenesis (Westerterp-Plantenga et al., 2005). Increased protein intake resulted in less weight regain in two studies testing the effect of 30 g/day (Lejeune et al., 2005) and 42.8 g/day (Westerterp-Plantenga et al., 2004) of added protein. Although both studies were relatively short in duration (see Table 3.2), both reported increased satiety in the participants receiving additional protein, with those who received the higher amount of protein regaining 50% less weight than the placebo group (Westerterp-Plantenga et al., 2004). In both studies, the actual consumption of protein was 18% of calories in the protein groups compared to 15% of calories from protein in the control groups (Lejeune et al., 2005; Westerterp-Plantenga et al., 2004). Neither the trial examining the effect of supplementing fiber (Pasman, Westerterp-Plantenga, Muls et al., 1997a) nor the evaluation of added carbohydrate with fiber, caffeine, and chromium picolinate (Pasman, Westerterp-Plantenga, & Saris, 1997b) found any difference in amount of weight regained between the intervention and control groups.

*VLCD followed by VLCD use in maintenance*

The results of three studies that included the occasional use of a VLCD during maintenance or provided foods after VLCD-induced weight loss indicated that weight regain was similar among the randomized groups (Agras, Berkowitz, Arnow, Telch, Marnell et al., 1996; Lantz, Peltonen, Agren, & Torgerson, 2003; Rytting, Flaten, & Rossner, 1997). For example, the group who received a late afternoon 239 kcal reconstituted drink, as part of a reduced-calorie diet to prevent overeating in the evening, regained a similar amount of weight as the reduced-calorie



diet only group. Weight maintenance after 24 months was the same for all groups whether or not a VLCD was included in the maintenance phase (Ryttig et al., 1997). An examination of two methods of using a VLCD for weight maintenance determined that weight regain was similar between those who used a VLCD intermittently and those who used a VLCD as needed, i.e., when their weight exceeded the end of weight-loss treatment weight by 3 kg; yet, clinically significant weight losses were maintained in a majority of both groups after two years of continued VLCD use (Lantz et al., 2003). Table 3.2 shows that participants randomized to one of four treatment groups to examine the effect of limiting food variety with pre-packaged meals and individualizing the pace of solid food reintroduction after a VLCD were not significantly different in weight-loss maintenance at the end the trial (Agras et al., 1996).

*VLCD followed by physical activity in maintenance*

Two randomized trials of weight-loss maintenance explored the role of physical activity after a VLCD (Borg, Kukkonen-Harjula, Fogelholm, & Pasanen, 2002; Fogelholm, Kukkonen-Harjula, & Oja, 1999). The trial conducted in only women compared a control group (no increase in exercise) to a walking group with a caloric expenditure goal of 1,000 kcal/week and a walking group with a goal of expending 2,000 kcal/week (Fogelholm et al., 1999). The other trial enrolled only male participants and randomized participants to resistance training, or walking, or control (Borg et al., 2002). Both studies offered counseling to follow a low-fat diet. Although neither study found a difference between groups in weight regain at the completion of the trial (Table 3.2), adherence to the exercise prescription was negatively correlated with weight gain ( $r = -0.43$ ,  $p < .01$ ), and resistance training reduced the regain of body fat mass in the sample of men (Borg et al., 2002). In the trial with women, a higher number of daily steps was significantly associated with weight-loss maintenance, and slightly better maintenance in the 1,000 kcal/week

group suggests that a moderate exercise prescription was easier to follow (Fogelholm et al., 1999).

### **3.4.3 Pharmacotherapy**

Table 3.3 lists the seven trials that used medication, either sibutramine (Early, Apovian, Aronne, Fernstrom, Frank et al., 2007; James, Astrup, Finer, Hilsted, Kopelman et al., 2000; Wirth & Krause, 2001) or orlistat (Davidson, Hauptman, DiGirolamo, Foreyt, Halsted et al., 1999; Hill, Hauptman, Anderson, Fujioka, O'Neil et al., 1999; Karhunen, Franssila-Kallunki, Rissanen, Valve, Kolehmainen et al., 2000; Sjöström, Rissanen, Andersen, Boldrin, Golay et al., 1998), with dietary instructions or dietary support in randomized maintenance interventions following a drug therapy weight-loss trial. Two sibutramine studies compared a 15mg/day dose to placebo (Early et al., 2007; Wirth & Krause, 2001), and one trial used 10 mg/day, which could be increased to a maximum of 20 mg/day if additional weight gain occurred (James et al., 2000). All three sibutramine studies found the drug to be superior in sustaining weight loss when compared to placebo (Early et al., 2007; James et al., 2000; Wirth & Krause, 2001). No difference was found between groups who received a continuous or periodically interrupted dose,  $p = .28$  (Wirth & Krause, 2001). However, one trial compared sibutramine and meal replacements to placebo and a traditional, reduced-calorie diet, making it difficult to discern which element of the drug therapy arm contributed to the efficacy of the intervention. Of note, a higher proportion of black participants in this trial failed to meet the eligibility criteria for the maintenance phase of a  $\geq 5\%$  weight loss (Early et al., 2007). The four orlistat studies all used 1-year maintenance interventions and found the medication to be more efficacious for promoting weight-loss maintenance than placebo (Davidson et al., 1999; Hill et al., 1999; Karhunen et al.,

2000; Sjöström et al., 1998). Participants who received continuous treatment with orlistat 120 mg/TID for 2 years (during weight loss and during weight maintenance) experienced the least amount of regain (Karhunen et al., 2000). Administering higher doses resulted in less regain (Davidson et al., 1999; Hill et al., 1999). In fact, Hill and colleagues found that a higher proportion of the group that received orlistat 120 mg TID regained  $\leq 25\%$  of their body weight compared to placebo,  $p < .001$  (1999).

#### **3.4.4 Behavior Therapy**

Ten studies used some form of a behavioral therapy in randomized trials for weight-loss maintenance. (Table 3.4). Perri and colleagues conducted five such studies between 1984 and 2001 in an effort to improve maintenance after behavioral weight-loss treatment. Early research by these researchers found weight regain to be attenuated by forming peer social support groups and receiving weekly therapist phone calls,  $p < .01$  (Perri, McAdoo, Spevak, & Newlin, 1984a), continued interventionist contact via mail and telephone,  $p < .05$  (Perri, Shapiro, Ludwig, Twentyman, & McAdoo, 1984b), particularly when combined with behavioral and problem-solving therapy during weight loss compared to behavior therapy only,  $p < .05$  (Perri, McAdoo, McAllister, Lauer, & Yancey, 1986), and including more treatment components in the intervention, i.e., behavior therapy, therapist contact, aerobic exercise, and social support  $p < .01$  (Perri, McAllister, Gange, Jordan, McAdoo et al., 1988). More recent findings by Perri et al. (2001) indicate that problem-solving therapy is significantly better at promoting weight maintenance compared to a no-contact control condition over a one-year maintenance period,  $p < .05$ . These results also suggest that problem-solving therapy may be superior to relapse-prevention training in longer-term maintenance (11-17 months),  $p = .013$  (Perri et al., 2001). The

sessions for the relapse-prevention training groups included didactic lectures designed to train participants in specific maintenance skills. The problem-solving therapy group meetings did not include didactic material but centered on therapist-led group discussions about solutions to participant-introduced weight management issues. The finding of an improved outcome in the problem-solving therapy group suggests that participants may have benefited more from the group discussions and less instructive methods.

Building on the results of Perri and colleagues, other researchers have investigated continued participant contact for weight maintenance with less definitive results after inpatient weight-loss treatment (Leibbrand & Fichter, 2002), using phone contact or optional pre-packaged meals (Wing, Jeffery, Hellerstedt, & Burton, 1996), and mailing personalized reports (Riebe, Blissmer, Greene, Caldwell, Ruggiero et al., 2005). In the maintenance study following 10 weeks of inpatient weight-loss treatment, the group randomized to the control condition did receive detailed materials to support long-term behavior change; some individuals also formed peer support groups (Leibbrand & Fichter, 2002). Riebe et al. (2005) mailed reports to the treatment group, individualized to the person's stage of change in the Transtheoretical Model of Health Behavior Change, but this did not influence weight maintenance as the treatment and control groups both regained about 3 kg (Riebe et al., 2005). See Table 3.4. Two studies by Wing and colleagues were published together (1996). In the first study, weekly phone calls to the treatment group inquiring about self-weighing and self-monitoring food and exercise behaviors did not influence weight regain; however, calls were made by individuals who were unknown to the participant (Wing et al., 1996). In the second study, participants randomly assigned to the treatment group were required to purchase pre-packaged meals if they wished to use them. No difference in weight regain was observed between the treatment and control groups. Of those

who chose to purchase the food boxes, weight regain was no different,  $p = .11$  (Wing et al., 1996). A study examining financial incentives for maintaining weight or for participating in weight-maintenance behaviors found that the two treatment groups were not different from the controls in the amount of weight they regained; all participants sustained about half of their lost weight (Kramer, Jeffery, Snell, & Forster, 1986). A study with African Americans that used a culturally-tailored intervention did not find a difference in weight regain between the clinic-visit-only usual care group and the two intervention arms, group counseling and staff-assisted self-help (Kumanyika, Shults et al., 2005). The average regain for all participants was minimal, but the initial weight loss achieved was only 1.2 kg. Being in the highest tertile of weight loss during the weight-loss treatment phase was the strongest predictor of overall loss and maintenance,  $p = .002$  (Kumanyika, Shults et al., 2005).

### **3.4.5 Physical Activity and Alternative Therapies**

Only two studies examined either the effect of a physical activity intervention or an alternative therapy method in randomized trials of weight-loss maintenance and are not represented in a table. While research has documented the importance of physical activity in weight loss and maintenance (Jakicic, Marcus, Gallagher, Napolitano, & Lang, 2003; Jakicic, Winters, Lang, & Wing, 1999; Perri, Martin, Leermakers, Sears, & Notelovitz, 1997; Schoeller, Shay, & Kushner, 1997; Tate, Jeffery, Sherwood, & Wing, 2007; Villanova, Pasqui, Burzacchini, Forlani, Manini et al., 2006; Wadden, Vogt, Foster, & Anderson, 1998), only one trial, not conducted after a VLCD, randomized participants to a weight-loss maintenance intervention that focused on the effect of physical activity in preventing weight regain. Leermakers and colleagues randomly assigned 67 participants to either an exercise-centered intervention or a weight-centered

intervention after a behavioral weight-loss study (1999). The weight-centered treatment focused on dealing with participant-introduced barriers to weight-loss maintenance, and the exercised-centered intervention focused on sustaining physical activity, e.g., organized biweekly exercise sessions, incentives for meeting exercise goals, and problem-solving for handling exercise lapses. While both groups regained weight during the trial and 6-month follow-up, the weight-centered group regained less weight,  $p < .01$  (effect size = .31), and ate fewer calories from fat,  $p < .05$  (effect size = .24), suggesting that the exercise-centered intervention might not have included enough emphasis on controlling dietary intake (Leermakers et al., 1999). The 12-week alternative therapy trial included 10 hours of group meetings and explored the effects of randomly assigning 92 participants to *qigong*, Tapas Acupressure Technique® (TAT), or a support group (Elder, Ritenbaugh, Mist, Aickin, Schneider et al., 2007). *Qigong* is an ancient Chinese healing discipline that consists of a combination of breathing, mental exercises, and physical movements. TAT merges acupressure with mental focusing to change stored energy patterns in the body. The support group reviewed handouts related to weight-loss maintenance. At the 3-month follow-up, the TAT group had regained significantly less weight (+0.1 kg) than the *qigong* group (+2.8 kg),  $p < .01$  (effect size = .36), and marginally less than the support group (+1.2 kg),  $p = .09$  (effect size = .24) (Elder et al., 2007).

### 3.5 SUMMARY OF STUDY EFFECT SIZES

Of the studies examined, 39% had fewer than 100 participants and might have been underpowered to detect a difference in treatment. Only the phone intervention study by Wing and colleagues reported a small-medium effect size of 0.30 for the difference between the

treatment and control groups (1996). Effect sizes noted in the tables ranged from a very small .01 (Ryttig et al., 1997) to a medium-large effect of .60 for the study comparing the medication sertraline to placebo (Wadden et al., 1995). This latter study reported that the difference between groups in weight regain was non-significant, although a medium-large effect size was found suggesting that a sample size of 30 participants was not large enough to detect the effect.

### **3.6 DISCUSSION**

The findings from this review show that a limited number of interventions tested in randomized clinical trials have been successful in assisting individuals to maintain their initial weight loss after treatment. The reviewed studies suggest that promising methods for reducing weight regain include some medications, inclusion of caffeine, added dietary protein, adherence to physical activity, continued weight-loss therapist contact, consuming fewer calories from fat, and alternative strategies such as acupuncture. A small number of studies detected a significant influence on weight regain. Maintenance of lost weight is a complex undertaking, and long-term data on weight-loss maintenance is still lacking. Over time, it becomes increasingly difficult for persons to continue to follow the weight-management strategies learned during the course of weight-loss, and the treatment of obesity may require the use of a continuous care model (Perri, Sears, & Clack, 1993) in order to help individuals sustain the lifestyle changes that promoted the initial weight loss.

Methodological limitations, e.g., small sample size, participant attrition, short treatment duration, and sample characteristics that limit generalizability, (e.g., mostly women, mostly White), suggest that replication of these clinical trials with attention to their methodological

limitations is needed. Many trials were limited by a lack of male and minority representation in the study sample. With the exception of one trial (Borg et al., 2002), the reviewed studies consisted of mostly or all women, limiting the generalizability of findings to women. One trial that enrolled nearly 50% men found that the effect of orlistat versus placebo was significant in women, but not in men over the 3 years (Richelsen et al., 2007). Few studies even reported on the ethnicity of participants, and all but one included predominantly white individuals. Early et al. (2007) found that a higher proportion of Blacks and African Americans failed to meet the eligibility criteria for randomization to the weight-maintenance intervention,  $\geq 5\%$  weight loss. The study that included only African American participants reported an overall small weight loss from pre-treatment through weight maintenance (Kumanyika, Shults et al., 2005). These two trials attest to potential ethnic differences in weight management that are not explored in trials with nearly all white participants. Another limitation of all but one of these trials (Wing, Tate, Gorin, et al., 2006) is that there was no specific identification of a theory-base for the RCT. The study by Wing and colleagues utilized self-regulation theory in the design of their intervention using the Internet to promote weight maintenance (2006), but otherwise the lack of theory-based interventions is a notable limitation to these trials.

Ten reviewed trials had attrition rates of more than 35%, complicating the interpretability of the findings and introducing the possibility of a selection bias (Ware, 2003), particularly in weight management studies where participants who have not lost/maintained weight may be more likely to drop out (Ayyad & Andersen, 2000). A strength of the randomized clinical trial is the intention-to-treat analysis, which incorporates all participants according to their randomized group assignment without consideration to withdrawal or departure from treatment (Fisher, Dixon, Herson, Frankowski, Hearn et al., 1990). However, a true intention-to-treat analysis



requires that all participants be followed to the end of the trial, which is often very difficult in longitudinal studies.

Nearly half the studies included in this review examined the efficacy of an intervention after a very-low-calorie diet. Perhaps because these diets result in greater initial weight losses in the short-term (Gilden Tsai & Wadden, 2006), several researchers have attempted to identify strategies for maintaining these significant weight reductions long term. A larger weight loss with VLCD has been found to be associated with a higher percentage of weight-loss maintenance after more than 2 years (Anderson, Konz, Frederick, & Wood, 2001), but some evidence suggests that there is a sizable variation in the percent of weight regained from initial losses at one-year (-7% to 122%) and five-year follow-up (26% to 121%) (Saris, 2001). Pharmacotherapy trials found sibutramine and orlistat to improve weight maintenance after VLCD as well as after initial treatment with the drug and a reduced-caloric intake. These medications may indeed be helpful tools in weight-loss maintenance when combined with an adjustment in dietary intake. It is important to recognize the role of lifestyle modification with reduced caloric intake and increased activity in obesity treatment in combination with orlistat and sibutramine, and that these medications are not without side effects. Sibutramine is associated with elevations in blood pressure and heart rate. Orlistat, which has recently become available as an over-the-counter medication (Alli), has gastrointestinal side effects like oily stools, fecal urgency and incontinence, or reduced fat-soluble vitamin absorption (Padwal, Li, & Lau, 2003). Additionally, these medications are only approved for up to two years of ongoing use (Padwal et al., 2003), and weight regain occurs after the medication is stopped (Apfelbaum et al., 1999). A recent population-based Canadian study found that discontinuation rates in the community were much

higher for both drugs than rates observed in clinical trials, and 98% of individuals had stopped taking the medication at 2 years (Padwal, Kezouh, Levine, & Etminan, 2007).

Other treatments noted to be effective after a VLCD included a green-tea mixture, additional dietary protein, and physical activity adherence. Because the efficacy of a green-tea mix was found in only one study and only the group of participants who tended to consume lower levels of caffeine, these results should be interpreted cautiously. Yet, a large observational study over 12 years recently found increases in caffeine consumption to be associated with less weight gain (Lopez-Garcia, van Dam, Rajpathak, Willett, Manson et al., 2006). The positive (Andersen, Jacobs, Carlsen, & Blomhoff, 2006; Du, Melchert, Knopf, Braemer-Hauth, Gerding et al., 2005; Greenberg, Dunbar, Schnoll, Kokolis, Kokolis et al., 2007) and negative effects (Du et al., 2005; James, 2004; Riksen, Zhou, Oyen, Jaspers, Ramakers et al., 2006) of caffeine on health have been debated. Consequently, the use of increased caffeine for weight-loss maintenance may be controversial.

The addition of protein to dietary intake resulted in less body weight regain, consisting of only fat-free mass, even when physical activity levels were similar between groups. The level of satiety was also higher in the group that consumed more protein, although actual dietary intake did not differ (Westerterp-Plantenga et al., 2004). While others have documented that higher protein diets resulted in greater weight loss in the short term (Due, Toubro, Skov, & Astrup, 2004; Foster, Wyatt, Hill, McGucki, Brill et al., 2003; Samaha, Iqbal, Seshadri, Chicano, Daily et al., 2003), the long-term effectiveness of this eating plan has not been well documented. The two protein trials examined here were three or six months in length; thus, additional exploration of the role of higher protein intake in the long-term is necessary.

The reviewed studies of physical activity and weight maintenance after weight loss via VLCD did not report a difference in regain between randomized treatment groups. However, higher levels of physical activity, i.e., estimated total energy expenditure (Borg et al., 2002) and daily steps taken (Fogelholm et al., 1999), were associated with improved maintenance. The exercised-focused intervention that followed behavioral weight-loss treatment found the exercise-group had a poorer outcome compared to the weight-focused group; however, there were no differences between the two groups in 24-hour estimated energy expenditure, as measured by accelerometer (Leermakers et al., 1999). This suggests that the group that was intended to have a greater emphasis on exercise perhaps, in reality, did not. In fact, inadequate adherence to the physical activity protocol may be a key reason why randomized trials frequently fail to find a relationship between physical activity and weight maintenance (Wing, 1999). The important role of physical activity in weight maintenance has been well documented (Donnelly, Smith, Jacobsen, Kirk, Dubose et al., 2004; Jakicic & Otto, 2005; Schoeller et al., 1997; Villanova et al., 2006; Wadden et al., 1998), with particular emphasis placed on the value of long-term adherence to physical activity (Pronk & Wing, 1994). Current recommendations for maintaining lost weight in adults include participation in a minimum of 60 to 90 minutes of moderate-intensity activity each day (Haskell, Lee, Pate, Powell, Blair et al., 2007), a level of physical activity that may be difficult for many individuals to achieve and or maintain.

The reviewed behavioral weight-loss maintenance interventions showed that maintaining contact with participants was influential in reducing weight regain. While ongoing communication with participants was beneficial for sustaining weight loss (Perri et al., 1986; Perri, McAdoo et al., 1984), the method of the continued contact could be important to the participants' success. For example, the telephone calls made by interviewers unknown to the

participants, not the participant's interventionist, did not result in an improved outcome (Wing et al., 1996). Additionally, using the Internet as a means of continued contact had mixed results with two studies reporting that Internet support was as effective in preventing regain as in-person contact (Harvey-Berino et al., 2004; Harvey-Berino, Pintauro, & Gold, 2002b), and two studies reporting that the Internet groups regained more weight than in-person groups (Harvey-Berino, Pintauro, Buzzell et al., 2002a; Wing et al., 2006). In fact, 70% of persons in one Internet group indicated at the 12-month assessment that they would have preferred to be in the group that met in-person (Harvey-Berino, Pintauro, Buzzell et al., 2002a), demonstrating the importance of participant acceptability of the intervention.

The findings of one reviewed study revealed that the more successful group had a lower intake of calories from fat (Toubro & Astrup, 1997). These results are supported by much of the weight-management literature (Astrup, Grunwald, Melanson, Saris, & Hill, 2000; Gerhard, Ahmann, Meeuws, McMurry, Duell et al., 2004; Howard, Manson, Stefanick, Beresford, Frank et al., 2006; Lindstrom, Peltonen, Eriksson, Louheranta, Fogelholm et al., 2006; Shick, Wing, Klem, McGuire, Hill et al., 1998). Yet, a recent 14-month study comparing the effects of a moderate-fat intake (30% of calorie intake) to a diet low in fat (20% of calorie intake) found improved long-term weight losses in the moderate-fat intake group; the authors indicated that dietary adherence in the moderate-fat group might have been easier to attain, and thus, more successful weight-loss outcomes resulted (Azadbakht, Mirmiran, Esmailzadeh, & Azizi, 2007). Others have noted improved adherence and weight loss with a moderate-fat intake in an 18-month trial (McManus, Antinoro, & Sacks, 2001). A Cochrane Review of randomized controlled weight-loss trials of low-fat diets compared to other diets found no significant benefit of low-fat diets over other types of weight-loss diets in maintaining long-term weight loss (Pirozzo,

Summerbell, Cameron, & Glasziou, 2002). Future research should explore the role of enhanced dietary adherence and a low-fat versus moderate-fat intake for weight management.

Acupressure was shown to have efficacy as an alternative treatment for weight-loss maintenance (Elder et al., 2007). However, this study included only 43 participants and was just 12 weeks in length after 12 weeks of weight-loss treatment, a time point that coincides with typical peak weight-loss (Jeffery et al., 2000). Another trial that examined acupressure for weight loss found no significant effect (Allison, Kriebich, Heshka, & Heymsfield, 1995). This area of treatment for weight-loss maintenance is relatively unexplored and might warrant further research in larger and long-term trials (Allison, Fontaine, Heshka, Mentore, & Heymsfield, 2001; Pittler & Ernst, 2005).

### **3.7 IMPLICATIONS FOR NURSING**

Medical care of the obese patient often includes treating obesity-related conditions like hypertension, hyperlipidemia, or type 2 diabetes mellitus without equal attention to the underlying contributing factor of weight. Assisting patients with weight-loss maintenance remains a formidable challenge for nurses as well as all health care professionals. It is imperative for nurses to understand that the clinical benefits of weight loss are only transient if the reduced weight is not maintained. Health care providers need to emphasize the favorable health effects that result from losing and maintaining a moderate 10% weight loss, and help each individual to have a realistic weight-loss goal (Klein et al., 2004). The National Heart, Lung, and Blood Institute and North American Association for the Study of Obesity have published a document specifying that a program of weight maintenance should be implemented after 6 months of

weight-loss treatment and that the practitioner has a responsibility for following the patient long term to encourage the maintenance of lost weight (2000). Nurses can make follow-up phone calls to stay in contact with and monitor the patient's progress, as this strategy was found to be beneficial for weight maintenance. By educating themselves, their fellow health care professionals, and patients about achieving and maintaining weight loss, nurses can contribute significantly as professional role models and supportive clinicians to addressing this major health problem.

### **3.8 CONCLUSION**

The lack of prolonged success in behavioral therapy for weight loss has been recognized for approximately 30 years (Brightwell & Sloan, 1977; Jeffery, Vender, & Wing, 1978; Stunkard & Penick, 1979). Longer weight-loss trials have helped individuals lose more weight initially (Jeffery et al., 2000), but extended maintenance of the weight loss is not necessarily realized. The reviewed studies found that weight-loss maintenance treatment with orlistat or sibutramine and dietary modification, supplementing caffeine or protein, following a lower-fat diet, adherence to physical activity, continued participant contact, problem-solving therapy, and the alternative treatment acupressure were effective in reducing weight regain after weight-loss treatment. Additional studies are needed to confirm and expand upon these findings. Future research should explore the safety and efficacy of orlistat and sibutramine beyond the 2-year time period currently approved by the Food and Drug Administration. Further investigation of innovative strategies to promote adherence to a lower dietary fat intake and physical activity will likely be beneficial in assisting with weight maintenance. Future research should determine the

most appropriate, cost-effective ways to maintain contact with and provide support to individuals in their weight maintenance efforts. Finally, the development of unexplored, novel strategies to promote weight maintenance is also imperative so that individuals are able to sustain the weight loss that they work so hard to achieve.

**Table 3.1 Internet**

<i>Study</i>	<i>N</i>	<i>Treatment</i>	<i>Length of WM Tx</i>	<i>Results</i>	<i>% Weight Change</i>	<i>Effect Size</i>
Harvey-Berino et al., 2002b	46 (37 women)  41 at end of trial  4% attrition  "mostly White"	<i>3-GROUP DESIGN:</i> <i>Control</i> -no treatment  <i>In-person therapist-led</i>  <i>Internet therapist-led</i>  Biweekly meetings in person or chat session with same behavioral content, self-monitoring diet & physical activity. Call or e-mail on alternate weeks.	22-week WM after 15 weeks of behavioral WL	<u><i>During WM:</i></u> All groups lost an average of 1.6 kg additional weight during the 22 weeks of WM with no between group differences, $p = .83$ .	25% of total weight loss experienced by the total sample during the trial was lost during 15 weeks of WM	.03
Harvey-Berino et al., 2002a	122 (104 women)  90 at end of trial  26% attrition  > 96% White	<i>3-GROUP DESIGN:</i> <i>Frequent in-person (FIP)</i> biweekly meetings  <i>Minimal in-person (MIP)</i> monthly meetings for 6 months, then no contact  <i>Internet support (IS)</i> biweekly chat sessions  Same behavioral content, self-monitoring diet & physical activity. Call or e-mail on alternate weeks, FIP & IS.	1-year WM after 24 weeks behavioral WL	<u><i>Prior to WL Rx through WM<sup>a</sup>:</i></u> <i>Frequent in-person</i> -10.4 ± 6.3 kg  <i>Minimal in-person</i> -10.4 ± 9.3 kg  <i>Internet</i> -5.7 ± 5.9 kg  $p < .05$ for between group differences. IS group sustained less WL than FIP & MIP.	More of the FIP & MIP groups maintained a ≥ 5% WL, $p < .02$ .  FIP: 84%  MIP: 81.3%  IS: 44.4%	.20



Table 3.1 Internet (Continued)

<i>Study</i>	<i>N</i>	<i>Treatment</i>	<i>Length of WM Tx</i>	<i>Results</i>	<i>% Weight Change</i>	<i>Effect Size</i>
Harvey-Berino et al., 2004	232 (194 women)  176 at end of trial  24% attrition  100% White	<i>3-GROUP DESIGN</i> <i>Frequent in-person (FIP)</i> biweekly meetings at local interactive T.V. (ITV) studio  <i>Minimal in-person (MIP)</i> monthly meetings at ITV studio for 6 months, then no contact  <i>Internet support (IS)</i> biweekly chat sessions  Same behavioral content, self-monitoring diet & physical activity. Call or e-mail on alternate weeks, FIP & IS.	1-year WM after 6 months behavioral WL via ITV (live group members with a televised therapist)	<u><i>Prior to WL Rx through WM<sup>a</sup>:</i></u> <i>Frequent in-person</i> -5.1 ± 6.5 kg  <i>Minimal in-person</i> -5.5 ± 8.9 kg  <i>Internet</i> -7.6 ± 7.3 kg  <i>p</i> = .22 for between group differences.	<u><i>Percent who maintained a ≥ 5% WL:</i></u>  FIP: 46%  MIP: 49%  IS: 62%  <i>p</i> = .23 for between group differences.	.08
Wing et al., 2006	314 (255 women)  291 at end of trial  7% attrition	<i>3-GROUP DESIGN:</i> <i>Control</i> monthly informational newsletter  <i>In-person</i> weekly group meetings for 1 <sup>st</sup> month, then monthly; submitted weekly weights via telephone system	18-month WM-subjects had lost ≥ 10% of body weight in the previous 2 years	<u><i>During WM<sup>a</sup>:</i></u> <i>Control</i> +4.9 ± 6.5 kg  <i>In-person</i> +2.5 ± 6.7 kg  <i>Internet</i> +4.7 ± 8.6 kg  <i>p</i> = .05 for difference between in-person	<u><i>Percent who regained ≥ 2.3 kg:</i></u> <i>Control</i> 72.4%  <i>In-person</i> 45.7%  <i>Internet</i> 54.8%	.11

Table 3.1 Internet (Continued)

<i>Study</i>	<i>N</i>	<i>Treatment</i>	<i>Length of WM Tx</i>	<i>Results</i>	<i>% Weight Change</i>	<i>Effect Size</i>
Wing et al., 2006 (continued)	Race/ ethnicity not reported	<i>Internet</i> weekly group meetings for 1 <sup>st</sup> month, then monthly via chat room; submitted weekly weights online		and control groups	$p = .008$ and $p < .001$ for difference between control & Internet and control & in- person, respectively.	

*Note.* WL= weight loss; WM= weight maintenance; Tx= treatment. <sup>a</sup>mean  $\pm$  standard deviation.

**Table 3.2 Treatment after a Very-Low-Calorie-Diet**

<i>Study</i>	<i>N</i>	<i>Treatment</i>	<u><i>Medication Use</i></u>		<i>% Weight Change</i>	<i>Effect Size</i>
			<i>Length of WM Tx</i>	<i>Results</i>		
Richelsen et al., 2007	309 (157 women)	<i>2-GROUP DESIGN: Orlistat 120mg TID</i>	3-year WM	<u><i>During WM<sup>a</sup>:</i></u> <i>Orlistat</i> +4.6 ± 8.6kg	<u><i>After 3 years:</i></u> <i>Men</i> Orlistat: -8.3% Placebo: -7.5%, <i>p</i> = ns	.13
	200 at end of trial 35% attrition Race/ethnicity not reported	<i>Placebo</i>  Both groups were prescribed a reduced calorie diet (-600 kcal/d); visits with dietary and lifestyle counseling every mo for 18 mo then every 3 mo thereafter	after 8-week VLCD	<i>Placebo</i> +7.0 ± 7.1kg  <i>p</i> < .02 for group differences	<i>Women</i> Orlistat: -8.4% Placebo: -5.3%, <i>p</i> < .02	
Laaksonen et al., 2003	41 (20 women)	<i>2-GROUP DESIGN: Orlistat 120mg TID</i>	1-year WM	<u><i>Prior to WL Rx through WM<sup>a</sup>:</i></u> -12.6 ± 7.4 kg for entire sample with no difference between groups, <i>p</i> -value not reported	<u><i>Those who lost ≥ 10%<sup>a</sup>:</i></u> Weight change in the last 6 months was +0.6 ± 2.3 kg	Unable to determine from data provided.
	34 at end of trial 17% attrition Race/ethnicity not reported	<i>Placebo</i>  Both followed a reduced-calorie and fat diet of at least 1200 kcal/d personalized according to estimated energy expenditure	after 9-week VLCD			

Table 3.2 Treatment after a Very-Low Calorie-Diet (Continued)

Study	N	Treatment	Length of WM Tx	Results	% Weight Change	Effect Size
LeCheminant et al., 2005	147 (107 women)	2-GROUP DESIGN: 2 meal replacements daily + meal plan	36-week WM after 12-week VLCD & 4 weeks of solid foods	<u>Weight after WL<sup>a</sup>:</u> <u>Meal replacements</u> 85.4 ± 14.3 kg	<u>During WM:</u> <u>Men</u> 4.9% increase in body weight, <i>p</i> < .05	.02
	92 at end of trial	Orlistat 120 mg BID + meal plan		Orlistat 120 mg 85.7 ± 17.9 kg	<u>Women</u> 2.4% increase in body weight, <i>p</i> = ns	
	41% attrition	In both groups the meal plan was to maintain weight; weekly group meetings in lifestyle modification until 26 weeks then biweekly thereafter.		<u>Weight after WM<sup>a</sup>:</u> <u>Meal replacements</u> 88.1 ± 16.5 kg		
	Race/ethnicity not reported			Orlistat 120 mg 88.5 ± 20.3 kg		
Mathus-Vliegen et al., 2005	189 (162 women)	2-GROUP DESIGN: Sibutramine 10mg/d- could increase to 15 mg after 6 mo if weight gain of > 3 kg	18-month WM after 10-week VLCD & 2 weeks of including solid foods	<u>Prior to WL Rx through WM<sup>a</sup>:</u> <u>Sibutramine</u> -10.7 ± 0.5 kg or -10.3 ± 7.0%	<u>During WM:</u> <u>Sibutramine</u> +4.1 kg or 4.5%	.21
	119 at end of trial	Placebo		Placebo -8.5 ± 8.1 kg or -7.9 ± 7.3%	Placebo +6.7 kg or 7.6%	
	37% attrition	Both groups had biweekly meetings with GP and dietitian for 2 mo, monthly until 12 mo & bi-monthly thereafter; 600 calorie-deficit/d			<i>p</i> = .004 for between group differences	
	>98% White					

Table 3.2 Treatment after a Very-Low Calorie-Diet (Continued)

<i>Study</i>	<i>N</i>	<i>Treatment</i>	<i>Length of WM Tx</i>	<i>Results</i>	<i>% Weight Change</i>	<i>Effect Size</i>
Apfelbaum et al., 1999	160 (127 women)  108 at end of trial  32% attrition  Race/ethnicity not reported	<i>2-GROUP DESIGN:</i> <i>Sibutramine 10mg/d</i>  <i>Placebo</i>  Both groups had dietary counseling to consume 20-30% less total calories than pre-weight loss intake; individual meeting with dietician every 3 months; assessments monthly	1-year WM after 4-week VLCD	<u><i>During WM<sup>a</sup>:</i></u> <i>Sibutramine 10mg/d</i> -5.2 ± 7.5 kg  <i>Placebo</i> +0.5 ± 5.7 kg  <i>p</i> = .004 for group differences	<i>Sibutramine</i> 75% of group sustained ≥ 100% of lost weight  <i>Placebo</i> 42% of group sustained ≥ 100% of lost weight  <i>p</i> = .004 for group differences	.23
Hauner et al., 2001	110 (84 women)  75 at end of trial  29% attrition  100% White	<i>2-GROUP DESIGN:</i> <i>Acarbose 50-300 mg/d</i> titrated weekly; 59.3% of group took 300 mg  <i>Placebo</i>  Both groups were advised to follow a personalized WM diet	26-week WM after 12-week VLCD	<u><i>During WM:</i></u> <i>Acarbose</i> no weight gain  <i>Placebo</i> +0.6 kg  <i>p</i> = .38 for group differences	<i>Acarbose</i> No weight change  <i>Placebo</i> 6% regain of lost weight	.09

Table 3.2 Treatment after a Very-Low Calorie-Diet (Continued)

<i>Study</i>	<i>N</i>	<i>Treatment</i>	<i>Length of WM Tx</i>	<i>Results</i>	<i>% Weight Change</i>	<i>Effect Size</i>
Wadden et al., 1995	53 (all women)	<b>2-GROUP DESIGN:</b> <i>Sertraline 200mg/d</i>	54-week WM after 26-week WL Rx with VLCD and behavior therapy	<u><i>During WM<sup>a</sup>:</i></u> <i>Sertraline</i> +17.7 ± 10.6 kg regained of the 26.3 ± 7.6 kg original loss  <i>Placebo</i> +11.8 ± 9.0 kg regained of the 23.4 ± 7.8 kg original loss  <i>p</i> = ns for between group differences	<i>Sertraline</i> 70.9 ± 41.7% <sup>a</sup> of lost weight regained  <i>Placebo</i> 46.5 ± 34.6% <sup>a</sup> of lost weight regained	.60
<b><u>Dietary, Macronutrient, and Other Supplementation</u></b>						
Toubro & Astrup, 1997	43 (39 women)	<b>2-GROUP DESIGN:</b> <i>Ad lib</i> 55% carb, 20-25% fat diet; 24-pg dietary booklet	1-year WM after 8 weeks VLCD with 1 year follow-up	<u><i>During WM:</i></u> <i>Ad lib</i> +0.3 (95% CI, -3.0 to 3.6) kg regained  <i>Reduced-calorie</i> +4.1 (95% CI, 1.2 to 6.9) kg regained  <i>p</i> = .08 for a group difference	<u><i>After 1 yr f/u:</i></u> <i>Ad lib</i> +5.4 (95% CI, 2.3 to 8.6) kg of initial 13.5 kg WL regained (40%)  <i>Reduced-calorie</i> +11.3 (95% CI, 7.1 to 15.5) kg of initial 13.8 kg WL regained (82%)  <i>p</i> = .03 for a group difference	.29
	37 eligible for WM					
	34 at end of trial	<i>Reduced-calorie</i> 7.8 MJ/d (1875 kcal) using 144 color-coded cards to represent foods, each card = 65.2 kcal				
	21% attrition					
	Race/ethnicity not reported	Both groups received a relapse prevention training program in weekly group meetings for 4 weeks & biweekly for 50 weeks				

Table 3.2 Treatment after a Very-Low Calorie-Diet (Continued)

<i>Study</i>	<i>N</i>	<i>Treatment</i>	<i>Length of WM Tx</i>	<i>Results</i>	<i>% Weight Change</i>	<i>Effect Size</i>
Pasman et al., 1997a	39 (all women)  31 at end of trial  20% attrition  Race/ ethnicity not reported	<i>2-GROUP DESIGN:</i> <i>Fiber 10 mg BID</i> 10 g guar gum BID  <i>Control</i>  Both groups had no dietary restrictions or physical activity advise; assessments at 2, 8 & 14 months with 3-day food diaries of food intake	14-month WM after 2-month VLCD	<u><i>During WM<sup>a</sup>:</i></u> <i>Group A</i> (consumed > 80% of fiber) +65 ± 65% regain of lost weight  <i>Group B</i> (consumed 50-80% of fiber) +123 ± 63% regain of lost weight  <i>Control</i> +61 ± 66% regain of lost weight	<i>Group A</i> 6/10 persons regained ≥ 50%  <i>Group B</i> 9/10 persons regained ≥ 50%  <i>Control</i> 7/11 persons regained ≥ 50%	.33
Pasman et al., 1997b	39 (all women)  33 at end of trial  15% attrition  Race/ ethnicity not reported	<i>3-GROUP DESIGN:</i> <i>50 g carbohydrate + 200 µg chromium-picolinate + 20 g fiber + 100 mg caffeine (CHO+)</i>  <i>50 g carbohydrate (CHO)</i>  <i>Control</i>  Both groups followed an ad lib diet; assessments at 4, 10 & 16 mo with 3-day food diaries of food intake	16-month WM after 2- month VLCD	<u><i>During WM<sup>a</sup>:</i></u> <i>(CHO+)</i> 51.1 ± 109.0% regain of lost weight  <i>(CHO)</i> 68.1 ± 55.2% regain of lost weight  <i>Control</i> 85.5 ± 55.8% regain of lost weight	<i>(CHO+)</i> 31% regained < 50% of lost weight  <i>(CHO)</i> 36% regained < 50% of lost weight  <i>Control</i> 21% regained < 50% of lost weight	CHO+ vs. Control = .40  Control vs. CHO = .31  CHO+ vs. CHO = .20

Table 3.2 Treatment after a Very-Low Calorie-Diet (Continued)

<i>Study</i>	<i>N</i>	<i>Treatment</i>	<i>Length of WM Tx</i>	<i>Results</i>	<i>% Weight Change</i>	<i>Effect Size</i>
Kovacs et al., 2004	104 (78 women)	<i>2-GROUP DESIGN:</i> <i>Green tea 450 mg/d</i> 2 capsules with each meal	13-week WM after 4-week VLCD	<u><i>During WM</i></u> <sup>a</sup> : <i>Green tea 450 mg/d</i> 30.5 ± 61.8% regain of lost weight	<i>High-caffeine consumer who received green tea</i> +39 ± 17% <sup>a</sup>	.18
	104 at end of trial	<i>Placebo</i>		<i>Placebo</i> 19.7 ± 56.9% regain of lost weight	<i>Low-caffeine consumer who received green tea</i> +16 ± 11% <sup>a</sup>	
	No attrition	No dietary or activity instructions specified		<i>p</i> = ns for group differences	<i>p</i> < .05 for group differences	
	Race/ethnicity not reported					
Westerterp-Plantenga et al., 2005	76 (53 women)	<i>2-GROUP DESIGN:</i> <i>Green tea-caffeine mix (150 mg caffeine/d)</i> 2 capsules with each meal	3-month WM after 4-week WL	<u><i>During WM:</i></u> Weight loss continued in the green-tea group with low caffeine intake and increased in both the placebo group with low caffeine intake as well as the green-tea group with high caffeine intake, <i>p</i> < .01 for group differences.	<i>Green tea + LC</i> -11.1 ± 24.3% <sup>a</sup> weight loss  <i>Placebo + LC</i> +40.8 ± 38.9% <sup>a</sup> weight regain  <i>Green tea + HC</i> +24.4 ± 18.7% <sup>a</sup> weight regain	.30
	76 at end of trial	<i>Placebo</i>				
	No attrition	Randomized after stratification for high caffeine (HC) intake (> 300 mg/d) and low caffeine (LC) intake (< 300 mg/d); food intake not assessed				
	Race/ethnicity not reported					



Table 3.2 Treatment after a Very-Low Calorie-Diet (Continued)

<i>Study</i>	<i>N</i>	<i>Treatment</i>	<i>Length of WM Tx</i>	<i>Results</i>	<i>% Weight Change</i>	<i>Effect Size</i>
Westerterp-Plantenga et al., 2004	148 ("women & men")	<i>2-GROUP DESIGN:</i> <i>Added protein</i> 48.2 g/d as 2 drinks	3-month WM after 4-week VLCD	<u><i>During WM<sup>a</sup>:</i></u>  <i>Added protein</i> 17.3 ± 60.3% regain of lost weight	50% less weight regained in added protein group compared to control	.16
	148 at end of trial	<i>Control</i>  Both groups followed an ad lib diet, counseling as needed from dietician		<i>Control</i> 36.6 ± 46.8% regain of lost weight		
	No attrition					
	Race/ ethnicity not reported			<i>p</i> < .05 for group differences		
Lejeune et al., 2005	120 ("women & men")	<i>2-GROUP DESIGN:</i> <i>Added protein</i> 30 g/d as 1 drink	6-month WM after 4-week VLCD	<u><i>During WM<sup>a</sup>:</i></u>  <i>Added protein</i> 19.6 ± 82.1% regain of lost weight	<u><i>Net weight loss after WM compared to pre- VLCD:</i></u>	.18
	113 at end of trial	<i>Control</i>  Both groups had monthly visits for 6 mo; allowed to eat usual diet; counseling as requested from dietician		<i>Control</i> 54.9 ± 65.8% regain of lost weight	<i>Added protein</i> -6.7 ± 7.2% <sup>a</sup>  <i>Control</i> -3.8 ± 4.8% <sup>a</sup>	
	6% attrition					
	Race/ ethnicity not reported			<i>p</i> < .05 for group differences	<i>p</i> < .05 for group differences	

Table 3.2 Treatment after a Very-Low Calorie-Diet (Continued)

**VLCD Use**

<i>Study</i>	<i>N</i>	<i>Treatment</i>	<i>Length of WM Tx</i>	<i>Results</i>	<i>% Weight Change</i>	<i>Effect Size</i>
Ryttig et al., 1997	81 (44 women)	<b>3-GROUP DESIGN:</b> <i>1600 kcal/d diet for WL &amp; WM (A)</i>	24-month WM after 2-month VLCD or 1600 kcal/d diet	<u><i>Prior to WL Rx to trial end<sup>a</sup>:</i></u> -10.9 ± 10.2 kg in all groups	<i>Group A</i> -7% overall	A vs. B = .21
	76 eligible for WM	<i>1600 kcal/d diet with 239 kcal of VLCD in WM (B)</i>			<i>Group B</i> -10% overall	A vs. C = .19
	42 at end of trial	<i>1600 kcal/d diet in WM (C)</i>		<u><i>Weight at end of Rx<sup>a</sup>:</i></u> <i>Group A</i> 110.7 ± 17.4 kg	<i>Group C</i> -9.5% overall	B vs. C = .01
	45% attrition	All were instructed to maintain same level of physical activity; monthly assessments for 7 months then every 7 weeks		<i>Group B</i> 107.3 ± 15.1 kg		
	Race/ethnicity not reported			<i>Group C</i> 107.5 ± 16.9 kg		
				NS group differences		
Lantz et al., 2003	334 (248 women)	<b>3-GROUP DESIGN:</b> <i>Intermittent VLCD</i> Repeat VLCD for 2 weeks every 3 <sup>rd</sup> month	2-year WM after 16-week VLCD	<u><i>Prior to WL Rx to trial end<sup>a</sup>:</i></u> <i>Intermittent VLCD</i> -6.2 ± 9.5%	<i>Intermittent VLCD</i> 44% maintained a ≥ 5% weight loss	.17
	117 at end of trial	<i>On-demand VLCD</i> Use VLCD when weight surpasses 3 kg above weight after VLCD		<i>On-demand VLCD</i> -7.7 ± 8.4%	<i>On-demand VLCD</i> 62% maintained a ≥ 5% weight loss	
	65% attrition			$p < 0.001$ for significant loss over time; $p = ns$ for group differences		
	Race/ethnicity not reported	Both had appointments biweekly for 6 months then monthly thereafter				

Table 3.2 Treatment after a Very-Low Calorie-Diet (Continued)

<i>Study</i>	<i>N</i>	<i>Treatment</i>	<i>Length of WM Tx</i>	<i>Results</i>	<i>% Weight Change</i>	<i>Effect Size</i>
Agras et al., 1996	194 (all women)	<i>4-GROUP DESIGN: Standard food + time dependent (S + T)</i>	9-month WM after 12-week	<u><i>Prior to WL Rx to trial end<sup>a</sup>:</i></u>	No significant differences in percent weight regain among the 4 groups after VLCD.	S+T vs. S+W = .03
	174 at end of trial	Regular food started 1 meal at a time at set intervals over 4 weeks	VLCD with follow up 9 months after WM	<i>S + T</i> -8.2 ± 12.3 kg		S+T vs. P+T = .19
	10% attrition	<i>Standard food + weight dependent (S + W)</i>		<i>S + W</i> -8.6 ± 11.4 kg		S+T vs. P+W = .35
	Race/ethnicity not reported	Regular food started only when weight stable over 1-3 months		<i>P + T</i> -6.0 ± 11.1 kg		S+W vs. P+T = .23
		<i>Pre-packaged food + time dependent (P + T)</i>		<i>P + W</i> -2.8 ± 18.3 kg		S+W vs. P+W = .38
		Prepackaged meals started 1 meal at a time at set intervals over 4 weeks		<i>p</i> = ns for group differences		P+T vs. P+W = .21
		<i>Pre-packaged food + weight dependent (P + W)</i>				
		Prepackaged meals started only when weight stable over 1-3 months				
		All received group behavior therapy in weekly meetings for 3 months, biweekly meetings for 3 months and monthly thereafter				

Table 3.2 Treatment after a Very-Low Calorie-Diet (Continued)

<i>Study</i>	<i>N</i>	<i>Treatment</i>	<i>Physical Activity</i>		<i>% Weight Change</i>	<i>Effect Size</i>
			<i>Length of WM Tx</i>	<i>Results</i>		
Fogelholm et al., 1999	82 (all women)	<i>3-GROUP DESIGN:</i> <i>Walk 1</i> Use 1000 kcal/week walking	40-week WM after 12-week VLCD	<u><i>During WM<sup>b</sup>:</i></u> <i>Walk 1</i> -0.7 (1.0) kg	Not reported	.15
	80 at end of trial	<i>Walk 2</i> Use 2000 kcal/week walking		<i>Walk 2</i> +0.2 (0.9) kg		
	2% attrition	<i>Control</i> No walking program		<i>Control</i> +1.7 (0.8) kg		
	Race/ethnicity not reported	All receive a low-fat diet, weekly group meetings, monthly materials on a healthy diet, pedometers		<i>p</i> = .18 for group differences		
Borg et al., 2002	90 (all men)	<i>3-GROUP DESIGN:</i> <i>Walking</i> 45-min sessions 3 times/week	6-month WM after 2-month VLCD with 23-month follow up	<u><i>During WM adjusted mean difference to control:</i></u> <i>Walking</i> +0.3 kg (95% CI, -2.2 to 2.8)	<u><i>At 23-month follow-up:</i></u> 47.5% of all participants regained > 10% compared to weight after WL Rx	.13
	82 at end of trial	<i>Resistance training</i> 45-min sessions 3 times/week		<i>Resistance training</i> -1.3 kg (95% CI, -3.8 to 1.1)		
	9% attrition	<i>Control</i> No increase in activity				
	Race/ethnicity not reported	All received a low-fat, ad-lib diet, weekly group meetings, food and exercise diaries		<i>p</i> = .25 for group differences		

Table 3.2 Treatment after a Very-Low Calorie-Diet (Continued)

*Note.* CI= confidence interval; GP= general practitioner; NS= non-significant; Tx= treatment; VLCD= very-low-calorie diet; WL= weight loss; WM= weight maintenance. <sup>a</sup>mean  $\pm$  standard deviation. <sup>b</sup>mean  $\pm$  stand error of the mean.

**Table 3.3 Pharmacotherapy**

<i>Study</i>	<i>N</i>	<i>Treatment</i>	<i>Length of WM Tx</i>	<i>Results</i>	<i>% Weight Change</i>	<i>Effect Size</i>
Early et al., 2007	148 (126 women)  133 eligible for WM  60 at end of trial  55% attrition  48% White 40% Black 9% Hispanic 1.5% Asian 1.5% Other	<i>2-GROUP DESIGN:</i> <i>Sibutramine</i> 15 mg/d + 1 meal replacement & 2 low-calorie meals (~1500 kcal/d)  <i>Placebo</i> 3 low-calorie meals (~1500 kcal/d)  Both received behavior therapy with self-monitoring, problem solving, social support	9-month WM after 3 months WL with sib. 10 mg/d and low-calorie diet	<u><i>During WM<sup>b</sup>:</i></u>  <i>Sibutramine</i> -2.5 ± 0.6 kg  <i>Placebo</i> +2.9 ± 0.6 kg  <i>p</i> < .001 for group difference	<u><i>During WM<sup>b</sup>:</i></u>  <i>Sibutramine</i> -2.9 ± 0.7%  <i>Placebo</i> +3.3 ± 0.7%  <i>p</i> < .001 for group difference	.28
Wirth & Krause., 2001	1102  1001 eligible for WM (768 women)  787 at end of trial  21% attrition  99.5% White	<i>3-GROUP DESIGN:</i> <i>Sibutramine ongoing</i> 15mg/d for 44 wks  <i>Sibutramine periodic</i> 15mg/d except for weeks 13-18 and 31-36 when placebo was received  <i>Placebo</i>  All received dietary advice; no formal dietary or behavior therapy	44-week WM after 4 weeks WL with sib. 15 mg/d	<u><i>During WM:</i></u>  <i>Sib. ongoing</i> -3.8 kg (95% CI, -4.4 to -3.2)  <i>Sib. periodic</i> -3.3 kg (95% CI, -3.9 to -2.6)  <i>Placebo</i> +0.2 kg (95% CI, -0.6 to 0.94)	<u><i>During WM:</i></u>  <i>Sib. ongoing</i> Lost an additional 4%  <i>Sib. periodic</i> Lost an additional 3.5%  <i>Placebo</i> Regained 0.2%	.10

Table 3.3 Pharmacotherapy (Continued)

<i>Study</i>	<i>N</i>	<i>Treatment</i>	<i>Length of WM Tx</i>	<i>Results</i>	<i>% Weight Change</i>	<i>Comment</i>
James et al., 2000	605  467 eligible for WM (390 women)  261 at end of trial  44% attrition  96.5% White	<i>2-GROUP DESIGN:</i> <i>Sibutramine</i> 10mg/d (increased up to 20mg/d if regain)  <i>Placebo</i>  Both groups received dietary counseling each month or every 2 weeks if desired	18-month WM after 6-month WL with sib. 10 mg/d	<u><i>Prior to WL Rx to trial end<sup>a</sup>:</i></u>  <i>Sibutramine</i> -8.9 ± 8.1 kg  <i>Placebo</i> -4.9 ± 5.9 kg  <i>p</i> <.001 for group difference	<i>Sibutramine</i> 43% sustained at least 80% of lost weight.  <i>Placebo</i> 16% sustained ≥ 80% of lost weight  <i>p</i> <.001 for group difference	.15
Sjöström et al., 1998	688 (567 women)  526 eligible for WM  435 at end of trial  17% attrition  Race/ethnicity not reported	<i>2-GROUP DESIGN:</i> <i>Orlistat</i> 120 mg/TID  <i>Placebo</i>  Both groups were to follow a weight-maintenance diet; received either orlistat or placebo during WL	1-year WM after 1-year WL with orlistat 120 mg/TID or placebo	<u><i>During WM:</i></u>  <i>Orlistat in WL</i> orlistat regained 2.4 [SE 0.6] kg less than placebo, <i>p</i> <.001  <i>Placebo in WL</i> orlistat lost 3.6 [SE 0.6] kg versus placebo, <i>p</i> <.001	<u><i>After 2 years:</i></u>  <i>Continuous orlistat</i> 57.1% maintained a WL > 5%  <i>Continuous placebo</i> 37.4% maintained a WL > 5%	.14

Table 3.3 Pharmacotherapy (Continued)

<i>Study</i>	<i>N</i>	<i>Treatment</i>	<i>Length of WM Tx</i>	<i>Results</i>	<i>% Weight Change</i>	<i>Effect Size</i>
Davidson et al., 1999	1187	<i>4-GROUP DESIGN:</i>	1-year WM after 1-year WL with orlistat 120 mg/TID or placebo	<u><i>During WM<sup>b</sup>:</i></u>	<u><i>During WM:</i></u>	.11
	880 eligible for WM (741 women)	Orlistat-treated group rerandomized for WM		<i>Orlistat 120 mg</i> +3.2 ± 0.45kg	<i>Orlistat 120 mg</i> 35.2% of lost weight regained	
		<i>Orlistat 120 mg TID</i>		<i>Orlistat 60 mg</i> +4.3 ± 0.57kg		
	403 at end of trial	<i>Orlistat 60 mg TID</i>		<i>Placebo</i> +5.6 ± 0.42kg	<i>Orlistat 60 mg</i> 51.3% of lost weight regained	
	54% attrition	<i>Placebo</i>				
	81% White 15% Black 4% Hispanic	All followed a WM diet; 4 seminars on strategies for WM; instruction in self-monitoring food intake and activity		Orlistat 120 mg regained less weight than other groups, <i>p</i> <.001	<i>Placebo</i> 63.4% of lost weight regained	
Hill et al., 1999	1313 (605 women)	<i>4-GROUP DESIGN:</i>	1-year WM after 1-year WL with a 1000 kcal/d deficit diet	<u><i>Prior to WL Rx to trial end<sup>b</sup>:</i></u>	<u><i>Percent who regained ≤ 25% of lost weight:</i></u>	.12
		<i>Orlistat 120 mg TID</i>		<i>Orlistat 120 mg</i> -8.20 ± 0.5%	<i>Orlistat 120 mg</i> 47.5%	
		<i>Orlistat 60 mg TID</i>		<i>Orlistat 60 mg</i> -6.66 ± 0.5%	<i>Orlistat 60 mg</i> 30.4%	
	537 at end of trial	<i>Orlistat 30mg TID</i>		<i>Orlistat 30 mg</i> -5.94 ± 0.6%	<i>Orlistat 30 mg</i> 32.3%	
	26% attrition	<i>Placebo</i>		<i>Placebo</i> -6.42 ± 0.7%	<i>Placebo</i> 29.9%	
	88% White 6% Black 5% Hispanic 1% Other	All followed a WM diet; behavioral & dietary counseling; visits biweekly for 1 mo, monthly until month 5, & bimonthly thereafter.				



Table 3.3 Pharmacotherapy (Continued)

<i>Study</i>	<i>N</i>	<i>Treatment</i>	<i>Length of WM Tx</i>	<i>Results</i>	<i>% Weight Change</i>	<i>Effect Size</i>
Karhunen et al., 2000	96	<i>2-GROUP DESIGN:</i>	1-year WM	<u><i>Weight after WL<sup>a</sup>:</i></u>	<u><i>During WM:</i></u>	.27
	88	<i>Orlistat (O)</i>	after 1-year	O+O	O+O	
	eligible for	120 mg TID	WL with	82.6 ± 11.4kg	24% of lost	
	WM	<i>Placebo (P)</i>	either	O+P	weight regained	
	72 at end of	TID	orlistat 120	87.7 ± 14.2kg		
	trial		mg TID or	P+O	O+P	
	(59 women)	Groups were prescribed	placebo TID	89.2 ± 19.0kg	48% of lost	
	18% attrition	a WM diet; because of		P+P	weight regained	
		assignment during WL,		88.2 ± 15.8kg		
		4 groups resulted after		<u><i>Weight after WM<sup>a</sup>:</i></u>	P+O	
		WL & WM:			69% of lost	
	Race/	O+O, O+P, P+O, P+P		O+O	weight regained	
	ethnicity not			85.7 ± 12.4kg	P+P	
	reported			O+P	37% of lost	
				94.0 ± 16.6kg	weight regained	
				P+O		
				89.7 ± 19.9kg		
				P+P		
				91.7 ± 16.0kg		

*Note.* CI= confidence interval; TID= three times a day; Tx= treatment; WL= weight loss; WM= weight maintenance. <sup>a</sup>mean ± standard deviation. <sup>b</sup>mean ± standard error of the mean.

**Table 3.4 Behavior Therapy**

<i>Study</i>	<i>N</i>	<i>Treatment</i>	<i>Length of WM Tx</i>	<i>Results</i>	<i>% Weight Change</i>	<i>Effect Size</i>
Perri et al., 1984a	56 (45 women)  43 at end of trial  23% attrition  Race/ ethnicity not reported	<i>2-GROUP DESIGN:</i> <i>Booster</i> review of WL Rx strategies  <i>Multicomponent</i> taught to form self-help groups, use problem-solving; weekly therapist calls and mailed in postcards of food intake/weight  Both groups received 6 biweekly group sessions	1-year WM after 14-week WL with behavior therapy; follow up 6 months later	<u><i>During WM</i><sup>a</sup>:</u> <i>Booster</i> -4.6 ± 11.1 lbs <i>Multicomponent</i> -12.8 ± 16.0 lbs  <u><i>WL at follow up</i></u> <i>Booster</i> -0.8 ± 7.9 lbs <i>Multicomponent</i> -10.0 ± 15.3 lbs	<i>Booster</i> 94% of lost weight regained  <i>Multicomponent</i> 25% of lost weight regained	.39
Perri et al., 1984b	129 (115 women)  99 at end of trial  23% attrition  Race/ ethnicity not reported	<i>2-GROUP DESIGN:</i> <i>Phone &amp; mail contact (P)</i> therapist calls, mailed postcards of food intake, exercise & weight for 6 months  <i>No-contact control (C)</i>  Initial WL Rx: randomization to non-behavioral therapy (NB), behavior therapy (B) or behavior therapy + relapse-prevention training (B+R) resulting in 6 groups after WM, these 3 WL groups plus either contact or control in WM.	6-month WM after 15-week WL with behavior therapy; follow up 6 months later	<u><i>WL at follow up</i><sup>a</sup>:</u> <i>B+R: P</i> -22.7 ± 25.1 lbs  <i>B+R: C</i> -6.5 ± 7.9 lbs  <i>B: P</i> -12.7 ± 9.2 lbs  <i>B: C</i> -13.8 ± 13.4 lbs  <i>NB: P</i> -13.6 ± 11.0 lbs  <i>NB: C</i> -6.9 ± 10.5 lbs	<u><i>Attained a net loss of ≥ 20 lbs at follow-up</i></u>  <i>Phone &amp; mail contact</i> 33.3%  <i>No-contact control</i> 13.7%  <i>p &lt; .05 for group differences</i>	.17

Table 3.4 Behavior Therapy (Continued)

<i>Study</i>	<i>N</i>	<i>Treatment</i>	<i>Length of WM Tx</i>	<i>Results</i>	<i>% Weight Change</i>	<i>Effect Size</i>
Perri et al., 1986	90 (76 women)  67 at end of trial  25% attrition  Race/ethnicity not reported	<i>2-GROUP DESIGN:</i> <i>Multicomponent (M)</i> taught to form peer groups, problem solve; mailed weekly postcards of food intake/weight; weekly call from therapist  <i>No-contact control (C)</i>  Initial WL Rx included randomization to behavior therapy ( <i>B</i> ) or behavior therapy + aerobic exercise ( <i>B+A</i> ) resulting in 4 groups: <i>B+A:M</i> , <i>B:M</i> , <i>B+A:C</i> , <i>B:C</i>	1-year WM after 20-week WL with behavior therapy; follow up 6 months later	<u><i>Weight at end of WM<sup>a</sup>:</i></u>  <i>B+A:M</i> 82.8±13.2 kg <i>B:M</i> 85.5±16.5 kg <i>B+A:C</i> 86.2±18.5 kg <i>B:C</i> 91.6±20.1 kg  <u><i>Weight at 6-mo f/u<sup>a</sup>:</i></u>  <i>B+A:M</i> 84.8±13.3 kg <i>B:M</i> 86.8±17.6 kg <i>B+A:C</i> 88.3±19.4 kg <i>B:C</i> 91.3±18.7 kg	Unable to determine from information provided.	.24
Kramer et al., 1986	87 (36 women)  85 at end of treatment  2% attrition  Race/ethnicity not reported	<i>3-GROUP DESIGN:</i> <i>Skills focus + \$</i> eating/exercise skills practice  <i>Weight focus + \$</i> general problem-solving, \$10 withheld if any weight regain  <i>No-contact control</i>  For two intervention groups, \$10 return of deposited money at monthly meeting.	1-year WM after 15-week WL with behavior therapy	<u><i>During WM<sup>a</sup>:</i></u>  <i>Skills focus + \$</i> +13.4 ± 10.4 lbs  <i>Weight focus + \$</i> +11.9 ± 12.8 lbs  <i>No-contact control</i> +10.3 ± 14.5 lbs  (5 lbs added to 6 self-reported weights)	<u><i>% of WL maintained<sup>a</sup>:</i></u>  <i>Skills focus + \$</i> 50.0 ± 38.3%  <i>Weight focus + \$</i> 59.4 ± 44.5%  <i>Control</i> 48.2 ± 90.1%	Skill focus+\$ vs. Weight focus+\$ = .13  Skill focus+\$ vs. Control = .25  Weight focus+\$ vs. Control = .12

Table 3.4 Behavior Therapy (Continued)

Study	N	Treatment	Length of WM Tx	Results	% Weight Change	Effect Size
Perri et al., 1988	123 (97 women)	<b>5-GROUP DESIGN:</b> <i>Therapist contact (TC)</i> biweekly group sessions	1-year WM after 1-year	<u>Prior to WL Rx through f/u<sup>a</sup>:</u> <i>TC</i> -11.4 ± 12.1 kg	<u>% of WL maintained:</u>  4 Rx groups 82.7%	.27
	91 at end of treatment	<i>TC + social influence (SI)</i> added peer-support and incentives for adherence	WL with behavior therapy; follow up 6 months later	<i>TC + SI</i> -8.4 ± 7.5 kg	<i>No-contact control</i> 33.3%	
	26% attrition	<i>TC + aerobic exercise (AE)</i> added up to 180 min/week of aerobic activity		<i>TC + AE</i> -9.1 ± 6.4 kg		
	Race/ethnicity not reported	<i>TC + SI + AE</i> all of the above		<i>TC + SI + AE</i> -13.5 ± 15.2 kg		
		<i>No-contact control</i>		<i>No-contact control</i> -3.6 ± 6.2 kg		
Perri et al., 2001	88	<b>3-GROUP DESIGN:</b> <i>Relapse-prevention training</i> recognizing high-risk times, coping, practicing handling challenging situations	1-year WM after 5-month	<u>Prior to WL Rx through WM<sup>a</sup>:</u>  <i>Relapse-prevention training (RPT)</i> -5.9 ± 6.4 kg	<u>% who lost and maintained ≥ 10%</u>  <i>RPT</i> 21.4%	.22
	80 at end of trial (all women)	<i>Problem-solving therapy</i> orienting self to problem, generating alternatives, decision making, evaluation	WL with behavior therapy	<i>Problem-solving therapy (PST)</i> -10.8 ± 8.7 kg	<i>PST</i> 35.3%	
	9% attrition	<i>No-contact control</i>		<i>No-contact control (C)</i> -4.1 ± 4.9 kg	<i>C</i> 5.6%	
	Race/ethnicity not reported	Two intervention groups attended biweekly meetings				

Table 3.4 Behavior Therapy (Continued)

<i>Study</i>	<i>N</i>	<i>Treatment</i>	<i>Length of WM Tx</i>	<i>Results</i>	<i>% Weight Change</i>	<i>Effect Size</i>
Wing et al., 1996	<u>Study 1</u> 53 (all women) 50 at end of trial 6% attrition	<i>2-GROUP DESIGN:</i> <u>Study 1: Telephone Phone</u> weekly calls re: self-weigh or self-monitor foods and exercise	1-year WM after 6-month WL with behavior therapy	<u>During WM<sup>a</sup>:</u> <u>Study 1</u> <i>Phone</i> +3.9 ± 1.1 kg  <i>Control</i> +5.6 ± 1.0 kg	<u>Study 1</u> 25% less weight regained in phone group compared to control	Study 1 = .30 Study 2 = .16
	<u>Study 2</u> 57 (no gender data) 48 at end of trial 16% attrition	<i>Control</i> no contact  <u>Study 2: Food Provision</u> <i>Optional foods</i> monthly group meetings + optional food boxes for a fee during 4 months of WM		<u>Study 2</u> <i>Optional foods</i> +4.2 ± 1.0 kg  <i>Control</i> +4.3 ± 1.1 kg	<u>Study 2</u> 32% of lost weight regained in both groups	
	Race/ ethnicity not reported	<i>Control</i> monthly group meetings		<i>p</i> 's > .28 for group differences		
Liebbrand & Fichter, 2002	109	<i>2-GROUP DESIGN:</i> <i>Maintenance</i>	18-month WM after	<u>Weight after WL<sup>a</sup>:</u> <i>Maintenance</i>	6.3% of weight was lost and maintained by the total sample during WL and WM with no difference between groups	.02
	91 at end of trial (all women)	Eight 45-min phone calls from therapist in 1 <sup>st</sup> 9 months; 4 calls during 2 <sup>nd</sup> 9 months	10-week inpatient WL Rx	120.9 ± 23.4 kg <i>Control</i> 118.3 ± 24.4 kg		
	16% attrition			<u>Weight after WM<sup>a</sup>:</u> <i>Maintenance</i> 118.7 ± 26.0 kg		
	Race/ ethnicity not reported	<i>Control</i> no support after discharge		<i>Control</i> 118.2 ± 24.0 kg		

Table 3.4 Behavior Therapy (Continued)

<i>Study</i>	<i>N</i>	<i>Treatment</i>	<i>Length of WM Tx</i>	<i>Results</i>	<i>% Weight Change</i>	<i>Effect Size</i>
Riebe et al., 2005	144 (112 women)  104 at end of trial  28% attrition  97% White	<i>2-GROUP DESIGN:</i> <i>Extended care</i> received 2 personalized reports in the mail at 9 and 12 mo  <i>Control</i> received general materials about diet and exercise at 9 and 12 mo  Both groups received same anthropometric, biochemical, and dietary variable reports at 12 and 24 months	18-month WM after 6-month WL with behavior therapy	<u><i>Weight at end of WL<sup>a</sup>:</i></u> <i>Extended care</i> 87.6 ± 15.9 kg  <i>Control</i> 84.1 ± 14.1 kg  <u><i>Weight at end of WM<sup>a</sup>:</i></u> <i>Extended care</i> 90.5 ± 16.9 kg  <i>Control</i> 86.9 ± 15.4 kg	The total sample maintained 48% of lost weight.	.22
Kumanyika et al., 2005	128 (116 women)  87 at end of trial  32% attrition  100% African American	<i>3-GROUP DESIGN:</i> <i>Group counseling</i> 6 meetings biweekly then monthly; reviewed topics and > focus on group discussion  <i>Staff-assisted self-help</i> resources to promote self-directed WM- pedometer, peer support, monthly calls  <i>Clinic visits only</i> No intervention, only brief advice from MD as requested	8- to 18-month WM after 10-week WL with behavior therapy adapted for culture	<u><i>During WM:</i></u> <i>Group counseling</i> -0.02 kg (95% CI, -1.7 to 1.8 kg)  <i>Staff-assisted self-help</i> +1.1 kg (95% CI, -0.3 to 2.5 kg)  <i>Clinic visits only</i> -0.04 kg (95% CI, -1.9 to 1.8 kg)  <i>p</i> = .55 for group differences	25% of the total sample lost and maintained ≥ 5% of initial weight	.05

Table 3.4 Behavior Therapy (Continued)

*Note.* CI= confidence interval; M= mean; Tx= treatment; WL= weight loss; WM= weight maintenance. <sup>a</sup>mean  $\pm$  standard deviation.

## 4.0 RESULTS MANUSCRIPT #1

### An Exploration of Racial Differences and Psychosocial Correlates of Weight Maintenance after a Behavioral Weight Loss Trial

#### 4.1 ABSTRACT

**Objective:** To investigate weight maintenance after a behavioral weight loss trial and explore whether or not differences in weight maintenance existed between black and white participants. We also examined low-fat diet experiences, barriers to healthy eating, self-efficacy, social support and stress as potential correlates of weight maintenance. **Methods:** A descriptive, ancillary study, PREFER II, was conducted at 18 months after the completion of a behavioral weight loss trial, PREFER, to assess weight maintenance. Race was self-identified by participants as Black or White. We weighed participants in light clothing with no shoes using the Tanita digital scale. We used the following scales to measure psychosocial variables: Experiences Following a Low-Fat Diet (ELF), Barriers to Healthy Eating (BHE), Weight Efficacy Lifestyle and Self-Efficacy for Exercise. Social support was measured using a composite variable of two subscales from the ELF and BHE. We assessed stress from four survey items. We used hierarchical multiple linear and logistic regression models to examine the relationship of independent variables with percent weight change and unsuccessful weight



maintenance defined as > 5% weight regain. **Results:** The sample ( $N= 107$ ,  $n= 81$  White,  $n= 26$  Black) was mostly female (86.0%) and married (70.8%) with a mean age of 46.3 years ( $SD = 6.9$  years). After controlling for age, gender, income, education and marital status, in general there was no significant difference in percent weight change ( $p = .55$ ) or unsuccessful weight maintenance ( $p = .53$ ) between the black and white participants in PREFER II; black and white individuals regained a similar amount of weight ( $M = 5.0\%$ ,  $SD = 6.6\%$  and  $M = 4.4\%$ ,  $SD = 5.6\%$ , respectively). Percent increase in the BHE and the effect of a stressful life event on eating were significantly associated with percent weight regain and unsuccessful weight maintenance,  $ps < .04$ . **Conclusions:** A difference between black and white participants in weight maintenance was not supported. However, innovative strategies need to be developed to help all individuals overcome barriers to following a healthful eating plan and cope with stressful life events in order to minimize weight regain.

## 4.2 INTRODUCTION

Obesity and overweight are pandemic (Roth, Qiang, Marban, Redelt, & Lowell, 2004). Moreover, racial and ethnic minority groups like black Americans have a higher prevalence of obesity, e.g. 54% of black women are obese vs. 30.2% of white women, and are unduly burdened by the health disorders associated with these conditions, e.g. hypertension and type 2 diabetes (Must, Spadano, Coakley, Field, Colditz et al., 1999). Although weight loss treatment in the last 20 years has succeeded in promoting weight loss among those seeking to lose weight (Jeffery et al., 2000), weight maintenance after loss has remained a substantial challenge as this undertaking requires long-term adherence to the changes in lifestyle that created the initial weight loss (Perri

& Foreyt, 2004). Correlates of long-term weight maintenance after a loss have not been clearly elucidated (Anderson et al., 2001), particularly among black persons who are affected by obesity in greater numbers (Kumanyika, Gary, Lancaster, Samuel-Hodge, Banks-Wallace et al., 2005).

Very few studies have even explored weight maintenance among racial minorities; however, some differences in weight management have been reported. For example, some researchers found that while black participants tend to achieve less weight loss during treatment, the amount of regain they experienced following the loss is either the same as or less than white participants (Kumanyika, Espeland, Bahnson, Bottom, Charleston et al., 2002; Rickel, Gibbons, Milsom, DeBraganza, Murawski et al., 2007; Stevens, Obarzanek, Cook, Lee, Appel et al., 2001). Others noted that black individuals regained weight more rapidly (Wing & Anglin, 1996). A small trial examining weight maintenance in black women found that a smaller reaction to hunger and cues for eating were marginally related to weight-loss maintenance (Walcott-McQuigg, Chen, Davis, Stevenson, Choi et al., 2002). Further research is needed to investigate this crucial aspect of weight management among black persons.

Psychosocial factors contributing to unsuccessful weight maintenance may include boredom (Smith, Burke, & Wing, 2000; Wing & Jeffery, 2003), ineffective coping or problem-solving abilities (Drapkin, Wing, & Shiffman, 1995; Kayman, Bruvold, & Stem, 1990), unrealistic weight-loss goals (Cooper & Fairburn, 2001; Dalle Grave, Calugi, Molinari, Petroni, Bondi et al., 2005; Giusti, Suter, Heraief, Gaillard, & Burckhardt, 2003), and a decrease in eating restraint or an increase in disinhibition (McGuire, Wing, Klem, Lang, & Hill, 1999; Niemeier, Phelan, Fava, & Wing, 2007; Wing & Hill, 2001). A recent review of factors related to weight loss maintenance and regain reported that self-efficacy, social support, improved coping skills and ability to deal with life stress were associated with successful maintenance (Elfhag &

Rossner, 2005). While increases in self-efficacy have been linked to successful weight loss (Warziski, Sereika, Styn, Music, & Burke, 2008), some research does not support an influence of self-efficacy on weight after active treatment (Linde, Rothman, Baldwin, & Jeffery, 2006). Regarding social support, Wing and Jeffery reported a significant influence on weight loss and maintenance for the group of participants recruited with friends, but the findings were confounded by the addition of financial incentives for weight maintenance in this group (1999). Additionally, stress has been shown to have a substantial influence on eating behaviors and weight management (Crowther, Sanftner, Bonifazi, & Shepherd, 2001; DePue, Clark, Ruggiero, Medeiros, & Pera, 1995), and a high stress level at baseline was predictive of weight gain over six years (Korkeila, Kaprio, Rissanen, Koskenvuo, & Sorensen, 1998). A study with 36 African American women found that those who were more overweight reported a higher level of stress, and over 50% felt that stress negatively influenced the management of their weight (Walcott-McQuigg, 1995). The impact of stress on weight maintenance after a behavioral weight loss trial is not well documented however.

Studies have focused on continuing a low-fat diet as a means of promoting weight maintenance (Astrup et al., 2000; Lindstrom et al., 2006; Shick et al., 1998; Swinburn, Metcalf, & Ley, 2001), but continuing to consume a diet low in fat may prove difficult long-term. Some individuals feel deprived when eating a diet low in fat; yet, the development of a distaste for fat has been reported in those who are adherent to a low-fat diet, supporting the continuation of the diet long-term (Urban, White, Anderson, Curry, Kristal et al., 1992). The role of individuals' experiences when following a low-fat diet in weight maintenance has been largely unexplored, particularly among black populations.

Barriers to weight maintenance exist related to dietary intake and healthy eating (Eikenberry & Smith, 2004; Vijan, Stuart, Fitzgerald, Ronis, Hayward et al., 2005). A weight maintenance study of barriers associated with healthy food intake in women found the principle barriers to healthy eating were individual concerns related to taste, not enough time or motivation, and the belief that healthy foods were more costly (Andajani-Sutjahjo, Ball, Warren, Inglis, & Crawford, 2004). Barriers for African American women include the cost of more healthful foods (Davis, Clark, Carrese, Gary, & Cooper, 2005), traditional preparation of cultural dishes and family members' eating expectations (Airhihenbuwa, Kumanyika, Agurs, Lowe, Saunders et al., 1996; Carter-Edwards, Bynoe, & Svetkey, 1998). Barriers to healthy eating need to be further examined to determine the full effect of their influence on weight maintenance.

The aims of this study were to 1) investigate if there were differences between black and white participants in long-term weight maintenance 18 months after a behavioral weight loss trial, in terms of percent weight change and successful weight maintenance ( $\leq 5\%$  regain), and 2) examine experiences associated with following a low-fat diet, barriers to healthy eating, self-efficacy for resisting eating and for exercising, social support, and stress as potential correlates of weight maintenance as well as whether or not racial group moderated the relationship of these variables with weight maintenance.

## 4.3 METHODS

### 4.3.1 Design Overview and Study Sample

This descriptive ancillary study, PREFER II, was conducted 18 months after the completion of a randomized clinical trial of behavioral weight loss treatment, PREFER. Individuals were recruited from the community for PREFER in three cohorts to participate in a year and a half trial that randomly assigned participants to receive their preferred dietary treatment or not (Preference-Yes or Preference-No) and to either a standard, reduced-calorie and reduced-fat diet or a lacto-ovo-vegetarian reduced-calorie and reduced-fat diet. Standard behavioral therapy for weight loss was used and participants met in weekly group meetings for the first 6 months, biweekly meetings for months 7-9 and monthly meetings during months 10-12. In the last 6-month maintenance phase of the trial, participants had no meetings and no contact with study personnel except to arrange the final study assessment. Detailed information regarding the design and findings of the PREFER trial have been previously published (Burke, Choo, Music, Warziski, Styn et al., 2006; Burke, Hudson, Warziski, Styn, Music et al., 2007; Burke, Styn, Steenkiste, Music, Warziski et al., 2006; Burke, Warziski, Styn, Music, Hudson et al., 2008). In summary, the mean weight loss at study end was between 4% and 8% for the four treatment groups with no significant difference in weight loss observed for individuals in the lacto-ovo-vegetarian diet groups from those in the standard diet groups; participants randomly assigned to Preference-No lost more weight than participants who were randomized to Preference-Yes (Burke, Warziski et al., 2008).

For PREFER II, we contacted participants by mail asking them to return for a follow-up assessment 18 months after they finished the PREFER trial. After two weeks of no response,

individuals were contacted by phone to request that they participate. During PREFER, participants were not informed that any type of follow-up study would take place and were not contacted prior to the letter requesting their participation in PREFER II. We collected data regarding weight and psychosocial predictors of weight maintenance (experiences associated with following a low-fat diet, barriers to healthy eating, self-efficacy for resisting eating and for exercise, stress, and social support). The inclusion criteria of the PREFER study dictated the eligibility criteria for PREFER II— persons were 18-55 years old at enrollment of the PREFER trial, agreed to be randomly assigned to their treatment preference or not and one of the two diet plans, had a BMI between 27 and 43 kg/m<sup>2</sup> inclusively, and had adequately completed a 5-day food intake diary. Persons were excluded from PREFER if they were diagnosed with a serious medical condition that necessitated a physician's management of diet or physical activity (e.g. diabetes, recent myocardial infarction), had physical restrictions affecting their ability to exercise, were pregnant or planning a pregnancy, were being treated for a psychological illness, reported drinking four or more alcoholic beverages daily, were currently or recently (within the past 6 months) enrolled in a weight loss program or taking weight loss medications, or reported no regular consumption of meat, fish or poultry. For PREFER II, participants needed to have completed the PREFER final assessment as this time point was the baseline of PREFER II. We conducted assessments at the School of Nursing at the University of Pittsburgh, the Clinical Translational Research Center at Montefiore University Hospital, or another location convenient for the participant such as their home or workplace. Between February 2006 and April 2007, 119 of the 132 persons (90%) in the three PREFER cohorts who completed the weight loss trial took part in PREFER II. Of those 119, two participants were pregnant and one participant revealed that she had developed a binge eating disorder; individuals who scored above a level (> 37) that

would suggest the presence of disordered eating symptoms on the Binge Eating Scale (Gormally, Black, Daston, & Rardin, 1982) were excluded from PREFER. Thus, these three individuals were excluded from PREFER II because they were not representative of the population from which the sample was to be drawn. Additionally, nine of the participants self-selected a race other than Black or African American or White (three Hispanic, three Asian, one Hawaiian Pacific, one Alaskan Native and one American Indian) and were not included in the analysis. Therefore, the total sample consisted of 107 participants, 81 white individuals and 26 black individuals.

#### **4.3.2 Measures**

The Tanita Digital Scale was used to measure weight in pounds with participants wearing light clothing and no shoes. For one out-of-town participant, we obtained a self-reported current weight. Self-reported weights have been shown to be valid in previous studies of middle-aged adults (Kuczmarski, Kuczmarski, & Najjar, 2001; Spencer, Appleby, Davey, & Key, 2002), and a 2-kg correction was added to the value to account for possible under-reporting, as others have done (Kramer et al., 1986; Linde, Jeffery, Finch, Ng, & Rothman, 2004; Palta, Prineas, Berman, & Hannan, 1982).

We measured psychosocial variables using the Experiences Associated with Following a Low-fat Diet Scale (ELF), Barriers to Healthy Eating Scale (BHE), Weight Efficacy Lifestyle Questionnaire (WEL), and Self-Efficacy for Exercise Scale (SEE). Social support was measured with a composite score of three items from the BHE scale and four items from the ELF scale that measure family and friend social support as determined by factor analysis (Burke, Kim, & Music, 2004; Kim, Burke, Music, Cartwright, Polakoski et al., 2004). Stress was assessed from

four survey items: “Have you had a major stressful event (such as marriage, new job, divorce, death in the family) in the last 18 months? If yes, please describe.” “On a scale of 0 (no effect) to 10 (most effect), how much did this stressful event affect your eating habits?” “On a scale of 0% to 100% of the time, how often does stress influence how you eat?” “On a scale of 0% to 100% of the time, how often do you use tricks to lower your stress level (deep breathing, journal writing, exercise, relaxing hobbies, time management, etc.)?” The survey was developed for PREFER II and was pilot tested in a group of women being counseled for weight loss who reported that it was easily completed. We administered the ELF, BHE and WEL in both PREFER and PREFER II while the SEE and the four survey items assessing stress were only administered in PREFER II.

The ELF is a 25-item scale developed and used in the Women’s Health Trial (Urban et al., 1992) and measured experiences believed to be associated with low-fat dietary maintenance—wellness (feeling healthier while on the diet), distaste (for fat), cost (time and money), inconvenience (adhering to the diet when not eating at home), deprivation (denied desired foods), and family (insufficient support from family). It has a 5-point scale (1 = strongly disagree to 5 = strongly agree) and was validated during the Women’s Health Trial ( $r = .26$  to  $.76$ ). Negatively worded items were reverse coded so that higher scores represent a more positive experience. Cronbach’s alpha for this study was satisfactory at .81 (Nunnally & Bernstein, 1994), similar to that of others (Kim et al., 2004).

The BHE is a 22-item scale in which participants rated various circumstances related to following the healthy eating plan (emotions, daily mechanics of following the eating plan, social support) on a scale of 1 (no problem) to 5 (very important problem). Example items include, “I have trouble estimating appropriate portion sizes” or “When I am very hungry, I have trouble



controlling what I eat.” Lower scores indicated fewer barriers. A shorter version of this scale was used in a previous weight loss study (Jeffery, Wing, Thorson, Burton, Raether et al., 1993). It was expanded for the PREFER trial and psychometric testing revealed a Cronbach’s alpha of .86; (Burke et al., 2004). Cronbach’s alpha for the sample in this study was .89 indicating excellent internal consistency.

The WEL questionnaire is a 20-item measure to assess self-efficacy for weight management (Clark, Abrams, Niaura, Eaton, & Rossi, 1991). This scale assessed the participant’s confidence in the ability to resist eating in different situations on a scale of 0-9, such as “I can resist eating when I am watching TV.” Higher scores indicate higher confidence. Psychometric properties are well-established with Cronbach alpha coefficients ranging from .70 to .90 (Clark et al., 1991). Cronbach’s alpha for this study was high at .94. The validity and reliability of this instrument has also been established in African American women (Dutton, Martin, Rhode, & Brantley, 2004).

The SEE scale was only administered at PREFER II and is a 9-item self-efficacy measure for exercise (Resnick & Jenkins, 2000) that asked persons to rate their confidence in their ability to exercise 3 times per week for 20 minutes given a variety of circumstances, e.g. you were busy with other activities or you felt tired. Good internal consistency has been reported with a Cronbach’s alpha of .92 (Resnick & Jenkins, 2000). Cronbach’s alpha coefficient for this study was similar at .93. The scale range is 0 (not confident) to 10 (very confident) and higher scores indicated greater confidence in the ability to exercise.

The items that comprised the social support variable are listed in Table 4.3. These items from the BHE and ELF questionnaires were combined as a measure of the participant’s perception of their social support from family and friends for following a healthful eating plan.

Items were recoded so that a lower score indicated less social support. In this study, the Cronbach's alpha of .78 indicated satisfactory internal consistency for the social support measure.

### 4.3.3 Statistical Analysis

SPSS (version 15.0, SPSS Inc., Chicago, IL 2006) was used for the analysis. Descriptive statistics (means, standard deviations, medians) were used to characterize the study sample. We used data from the final PREFER assessment (considered the baseline assessment for PREFER II) and the 18-month follow-up, PREFER II. Percent change scores were calculated for all predictor variables (ELF, BHE, WEL, social support) and the continuous dependent variable (weight), with the exception of the SEE and the four stress items, as these variables were collected only at PREFER II. We calculated percent change scores as:

$$\frac{\text{PREFER II variable} - \text{PREFER trial completion variable}}{\text{PREFER trial completion variable}} \times 100 = \% \Delta \text{ variable (variable change)}$$

For the binary outcome variable, the percent change in weight maintenance was dichotomized as  $\leq 5\%$  regain (successful weight maintenance, coded as 0) or  $> 5\%$  regain (unsuccessful weight maintenance, coded as 1). We conducted a detailed exploratory analysis of all data using exploratory analytic techniques to assess missing data, screened for outliers, and determined whether assumptions underlying statistical tests were met. Missing data were identified and examined in SPSS; all participants and variables had  $< 5\%$  missing data. Exploration of patterns of missing data revealed that data were missing completely at random, Little's MCAR test  $\chi^2_{(26)} = 16.72, p = .92$ . Two participants were missing the ELF, BHE, and

WEL at baseline; one participant was missing only the ELF at baseline; one participant was missing income and marital status data; and one participant was missing the three continuous stress items. Because such a small amount of data was missing, a listwise deletion was used and these individuals were excluded from models that included these variables. Sociodemographic variables, baseline values of the independent variables, and weight and were examined for differences between black and white participants as well as between those who returned for PREFER II and those who did not return using chi-square tests of independence and Fisher's exact tests (categorical variables) and *t*-tests or Mann Whitney U tests (continuous variables). The significance level for two-sided hypothesis testing was set at .05.

Psychosocial correlates were examined in relation to weight maintenance as a continuous (% weight change) and binary outcome variable (successful vs. unsuccessful weight maintenance) using multiple linear and multiple binary logistic regression models, respectively. Assumptions underlying multiple linear regression (normality of the residuals, homoscedasticity of error variance, independence of observations, linearity of variables, no multicollinearity, no outliers) were assessed by examining histograms and normal probability plots of the studentized residuals, scatterplots of standardized predicted values versus standardized residual values, and scatterplots of the dependent variable versus the standardized residuals. All assumptions, with the exception of no outliers, were supported, e.g., histograms of residuals approximated a bell curve (normality), plots of standardized residuals with standardized predicted values were randomly scattered around a horizontal line at zero with no discernable pattern (homoscedasticity and linearity), standardized predicted values versus the dependent variable were randomly scattered around a line (linearity). Statistical assumptions of logistic regression (independence of observations; the independent variables are linearly related to the log odds; i.e. logit, of the

dependent variable; no multicollinearity; no outliers) were also supported, with the exception of no outliers. Linearity in the logit was assessed using the Box-Tidwell Transformation test by adding to the logistic models interaction terms of the cross product between each predictor variable (age, education, % change in ELF, % change in BHE, % change in WEL, % change in social support, the three continuous stress items) and its natural logarithm. None of these interaction terms were significant ( $ps > .15$ ); thus linearity in the logit was supported. In all logistic regression models, the reference group was the successful weight maintainers. Multicollinearity was assessed by examining the correlation matrix for all variables, variance inflation factors (VIF), tolerance and condition indices (CI). All correlations were  $< .80$ , all VIF values were  $< 10$ , all tolerance values were  $> .1$ , and all CI were  $< 30$  satisfying the assumption of no multicollinearity (Tabachnick & Fidell, 2001). Goodness of fit for the logistic models was assessed using the Hosmer-Lemeshow (H-L) test; all models showed satisfactory fit with non-significant H-L tests ( $ps > .07$ ) (Hosmer & Lemeshow, 2000). Diagnostics used to assess for possible outliers included examination of residual plots for data points that were far away from the distribution, standardized residuals, studentized deleted residuals, leverage values, Mahalanobis distance values, Cook's distance values, Dfbeta values, and deviance (for the logistic models). Sensitivity analyses were performed without participants who had outlying values to determine the influence of outliers on the estimation of regression coefficients and fitted/predicted values.

Predictors of interest were examined univariately first using simple linear and simple logistic regression models in order to select discriminating variables for inclusion in multivariate models. The SEE score was not a significant predictor of weight maintenance in either the simple linear or simple logistic regression models ( $ps > .76$ ), and thus was not included in the

multivariate regression models. We built the multiple linear and logistic models hierarchically controlling for age, gender, education, income, and marital status in the first block. For the first aim of the study, to investigate if there were differences between racial groups in weight maintenance after controlling for the above covariates, a linear and logistic model included only a dummy coded variable for race in the second block. For the second aim, in another linear and logistic model, psychosocial variables of interest (ELF, BHE, WEL) were added in the second block after including sociodemographic covariates in the first block, and race was added in the third block to determine its effect on weight maintenance after controlling for other variables. Because the social support variable was derived from items in the ELF and BHE, we wished to avoid multicollinearity and built separate hierarchical linear and logistic models to examine the effect of social support, with sociodemographic covariates in the first block, social support in the second block, and the race variable added in the third block. We attempted to derive a composite stress score from the three continuous items related to stress; however, the first item was only answered by individuals who reported experiencing a stressful event in the previous 18 months ( $n = 69$ ), and an exploratory factor analysis revealed that the remaining two items had a low correlation,  $r = -.03$ . Therefore, stress was examined in three linear and three logistic models with each stress item examined individually using the total sample for two items and the subsample ( $n = 69$ ) for one item. Interaction terms between race and all psychosocial predictors were included in the fourth blocks of linear and logistic models to assess for possible effect modification, i.e. moderation, due to racial group; however, no interaction terms were significant ( $ps > .10$ ). Thus, interaction terms were dropped from the models in the interest of parsimony, and effect modification due to racial group was not supported. Higher order effects for each predictor variable (cubic and quadratic terms) were also explored to improve fit and prediction.

Prior to creating higher order effect terms, continuous variables were centered by subtracting the mean value for the variable from each data point. The quadratic term for BHE was significant in the logistic regression model; however, after further examination of the residual plots, the curvature appeared to be the result of two outlying values. After the deletion of two additional outliers, the quadratic term was no longer significant. Please see Tables 4.8 and 4.9 for results with and without these influential outliers. Otherwise, the data did not reflect curvature in the plots, no other higher order terms were significant (all  $p > .11$ ) and did not improve model fit.

A total of three outliers were identified that overly influenced the findings for the predictors of WEL change and BHE change; these individuals were all women and were excluded from the multivariate linear and logistic models with ELF change, BHE change, and WEL change. One 53-year-old white woman experienced a 262.0% increase in self-efficacy for resisting eating, yet she regained 6.25% of her weight and was an *unsuccessful* weight maintainer. She had a 2.91% (7.7 lbs) weight loss during PREFER and had the lowest baseline score for self-efficacy for PREFER II. Despite the sizable increase in her self-efficacy during the 18-month period, her score remained in the lowest quartile of the sample at follow-up. She experienced stressful life events that included personal illness, family stress and financial problems that had an 8/10 influence on her eating habits, on a scale of 0 (no effect) to 10 (most effect). Another 47-year-old white woman had a 126% increase in barriers to healthy eating, and regained 3.82% of her weight making her a *successful* weight maintainer. She lost only 0.96% (2 lbs) of her weight during PREFER. Her baseline PREFER II BHE score was in the bottom 20% of the sample, but increased to the highest quartile of the sample at follow up. She reported job stress as a stressful event that had a 7/10 impact on her eating habits. The third outlier, a 46-year-old black woman, experienced a 123% increase in barriers to healthy eating, but regained 4.07%

making her a *successful* weight maintainer. She had also gained weight (0.65% or 1.7 lbs) during PREFER. Her PREFER II baseline BHE score was the fifth lowest score in the sample and increased to the 50<sup>th</sup> percentile at follow up. She reported the death of a significant other under stressful events that had a 7/10 influence on her eating habits.

#### 4.4 RESULTS

One hundred and seven black and white participants took part in PREFER II. Sociodemographic and baseline sample characteristics are noted in Table 4.4. Most individuals were female (86%), employed full time (79.1%), and highly educated ( $M = 15.3$  years,  $SD = 2.6$  years). There were no significant differences in sociodemographic variables between black and white participants (all  $p > .11$ ) with the exception of marital status. There were significantly more white individuals who were married or living with a partner compared to black persons,  $\chi^2_{(1)} = 10.08$ ,  $p < .01$ ; therefore marital status was controlled for in the analysis. There were also no differences in baseline independent or dependent variables (ELF, BHE, WEL, social support, weight) between racial groups, all  $p > .17$ . For the successful and unsuccessful weight maintainers, no significant differences between the baseline independent variables were found, all  $p > .06$ ; however, those who successfully maintained their weight weighed significantly more at baseline than those who did not ( $M = 201.2$  lbs,  $SD = 30.8$  lbs and  $M = 184.2$  lbs,  $SD = 34.2$  lbs, respectively,  $t_{(105)} = 2.69$ ,  $p < .01$ ). An examination of individuals who did not return for PREFER II revealed that there were no significant differences in sociodemographic (age, gender, race/ethnicity, education, income, marital status) or baseline variables (weight, ELF, BHE, WEL, social support) between those who participated in the PREFER II study and those who did not,  $ps > .08$ , supporting the

generalizability of these results to the entire PREFER sample. Additionally, there were no differences in the above variables between the nine participants who self-selected a racial group other than Black or White and those included in the analysis, all  $p > .15$ .

Table 4.3 shows the independent and dependent variables for the total sample and each racial group. A greater proportion of participants were successful weight maintainers (57%) compared to unsuccessful maintainers in the total sample and each group. The percent weight change for the total sample was a gain of a mean of 4.6% ( $SD = 5.8\%$ ), with no difference between black and white persons in either the binary outcome or the continuous outcome,  $ps > .65$ . Additionally, 57.3% of participants remained at or below what they initially weighed when they began the PREFER weight loss trial with 28.2% maintaining at least a 5% weight loss from the start of PREFER (data not shown). Most independent variables did not change much during the 18-month time frame with the exception of barriers to healthy eating, which increased by a mean of 12.7% ( $SD = 30.5\%$ ). This increase was similar in both black and white participants,  $U = 1003.0$ ,  $p = .86$ . In fact, there were no significant differences between the two racial groups in any of the independent variables, all  $p > .12$ . For the total sample and both racial groups, the mean percentage of the time that stress influenced eating habits was over 53%, yet the mean percentage of the time participants utilized techniques to reduce stress was less than 39% of the time. For the subsample of 69 individuals who experienced a stressful event in the 18-month period, the mean impact the event had on eating habits was 7.0 out of 10.0 for the total sample and white persons and 7.2 out of 10.0 for the black persons.

Results of the first linear model examining only race as a predictor of weight maintenance after controlling for age, gender, education, marital status, and income are presented in Table 4.4. Race was not a significant predictor of weight change,  $p = .55$ . In the multivariate



logistic model, race was also not found to significantly predict unsuccessful weight maintenance,  $p = .71$ , after adjusting for the effects of age, gender, education, marital status, and income. See Table 4.5.

Table 4.6 shows the results of the multivariate linear regression of ELF change, BHE change, and WEL change predicting weight change. ELF change and WEL change did not significantly predict weight change,  $p = .16$  and  $p = .51$ , respectively; however, BHE change was found to be a significant predictor of weight change. A 10% increase in barriers to healthy eating was associated with a 0.77% increase in weight after adjusting for the effects of other independent variables in the model,  $p < .01$ . The top five barriers are presented in Table 4.7 with the percentage of participants for each barrier who selected *somewhat important* or *very important* problem for me. The top four barriers were the same for everyone. However, for the total sample, successful maintainers, and white participants, the fifth barrier was *I use food as a reward or treat for myself*, whereas for the unsuccessful maintainers and black participants, *Resisting tempting high fat/high calorie foods in my work setting is difficult* was the fifth top barrier. Over 60% of all groups had difficulty staying motivated to keep off the weight they had lost and controlling what they ate when very hungry. Fewer successful maintainers had difficulty finding time for planning appropriate meals (39.4%) compared to unsuccessful maintainers (52.0%).

In Table 4.8, the multivariate results of the logistic model including ELF change, BHE change, and WEL change are presented including the two outliers on BHE score. In this analysis, age, BHE change and the quadratic effect for BHE change were significant predictors of unsuccessful weight maintenance. However, in Table 4.9, after the influential outliers were removed, the quadratic effect for BHE change became non-significant,  $p = .55$ , and race became

significant,  $p = .04$ . In this model, for every one-year increase in age, individuals were 1.11 times more likely to be successful at weight maintenance,  $p < .01$ , holding all other independent variables constant. For every one-percent increase in BHE, the odds of being an unsuccessful weight maintainer are 1.044 higher (95% CI = 1.02-1.07),  $p < .01$ , if all other independent variables are held constant. Additionally in this model, black participants had 3.81 (95% CI = 1.04-14.06) times the odds of being unsuccessful at weight maintenance,  $p = .04$ , compared to white participants, holding other independent variables constant.

Percent change in social support was not found to be a significant predictor of weight change in the multivariate linear regression model ( $b = -0.019$ ,  $SE = 0.025$ ,  $p = .45$ ) or of unsuccessful weight maintenance in the logistic model (OR = 0.99, 95% CI = 0.97-1.01,  $p = .35$ ). Effect modification with racial group was not supported as the interaction of race with social support was not significant in either the linear ( $b = -0.05$ ,  $SE = 0.06$ ,  $p = .42$ ) or logistic models (OR = 1.02, 95% CI = 0.97-1.06,  $p = .47$ ).

Sixty-four percent ( $n = 69$ ) of participants reported experiencing one or more stressful life events in the 18 months between PREFER and PREFER II. Eighty-nine stressful life events were reported that fell into three main categories: family or significant other-related, work-related, and personal. Family or significant other-related events included illness, death, and parenting, family, or relationship stress. The work-related category included any stressful events related to the person's employment, e.g. difficult boss, problems with co-workers, job loss. Personal stressful events included personal injury or illness, relocating, marriage, financial problems, and going to college. The greatest proportion of events related to one's family or a significant other, as seen in Figure 4.1. While most participants ( $n = 48$ ) reported only one stressful event, 13 individuals experienced two events and eight individuals experienced three

events in the 18-month time frame. In the multiple linear and logistic regression models, how much the stressful event affected eating habits (on a scale of 0 [no effect] to 10 [most effect]) was predictive of weight change. Table 4.10 shows the results of the linear model, and the logistic findings are presented in Table 4.11. A one-unit increase in the effect of the stressful event on eating was associated with a 0.51% increase in weight in the linear model ( $p = .04$ ) after adjusting for the effects of other covariates in the model. The odds of being an unsuccessful weight maintainer are 1.3 times higher for each unit increase in the effect of the stressful life event,  $p = .02$ , holding all other independent variables constant.

When examining stress in the total sample using the item *how often does stress influence how you eat*, the mean percentage of time participants reported that stress influenced how they ate was a little more than half the time (Table 4.3). There was not a significant prediction of weight change by this item in the multivariate linear regression model ( $b = 0.021$ ,  $SE = 0.020$ ,  $p = .31$ ). This item was marginally associated with unsuccessful weight maintenance in the logistic model ( $OR = 1.01$ ,  $95\% CI = 0.99-1.03$ ,  $p = .07$ ). The reported mean percentage of the time that participants used techniques to reduce stress was approximately 38% (Table 4.3). The item *how often do you use tricks to lower your stress level* was not a significant predictor of weight maintenance in either the multivariate linear model ( $b = -0.03$ ,  $SE = 0.02$ ,  $p = .17$ ) or logistic model ( $OR = 0.99$ ,  $95\% CI = 0.98-1.01$ ,  $p = .29$ ). Racial group was not a significant predictor in the linear or logistic models with the stress items ( $ps > .45$ ) and the interaction terms of race with the stress items were not significant in either the linear or logistic models ( $ps > .10$ ).

## 4.5 DISCUSSION

Weight maintenance in PREFER II at 18 months after a behavioral weight loss trial was moderate with participants regaining an average of 4.5% of their weight. The majority of individuals were successful at maintaining their weight with 58% of white participants and 54% of black participants regaining  $\leq 5\%$  from the completion of PREFER to PREFER II. Because a longer duration of successful maintenance has been associated with a greater chance of longer-term maintenance (Wing & Phelan, 2005), these successful participants might be able to look forward to continued success. The importance of weight maintenance over time must be viewed in the context of typical weight change as studies have found that untreated obese individuals may gain from 1 kg to 6.7 kg over the course of 5 years (Kumanyika, Obarzanek, Stevens, Hebert, & Whelton, 1991; Rothacker, 2000; Williamson, 1993). The proportion of individuals in PREFER II who regained  $\leq 5\%$  is similar to what others have found following behavioral weight loss treatment. Befort and colleagues followed 179 former weight loss participants an average of 14 months after they had completed behavioral treatment and found that 42% had regained  $< 5\%$  of their end-of-treatment weight compared to 58% who gained  $\geq 5\%$  (2007). Others have reported that 78% of the sample gained  $< 5\%$  of their weight 2.2 years after a behavioral program that promoted consumption of foods with a low-energy density (Greene et al., 2006). A study of weight loss maintenance after completion of a commercial weight loss program reported that 60.1% had maintained at least a 5% weight loss at 2 years (Lowe et al., 2001). Approximately 70% of individuals participating in a trial specifically targeting weight loss maintenance regained  $< 5\%$  of lost weight at one year (Harvey-Berino, Pintauro, Buzzell et al., 2002). Thus, the number of individuals in PREFER II who were successful at maintaining their weight is comparable to previous studies.

Racial differences in weight maintenance were generally not noted in this sample. White persons regained about 4.5% of their weight while black individuals regained 5%. Race did not significantly predict weight maintenance with the exception of one logistic model where black participants were more likely to be classified as unsuccessful weight maintainers compared to their white counterparts. An explanation for this finding is not readily apparent, but a result of categorizing a continuous variable, as we have done for the percent weight change outcome, is a loss of information that typically reduces measurement precision (Zhao & Kolonel, 1992), which might have affected the significant findings for race in this one binary logistic model. Yet, the results of the same linear regression model are in the same direction, supporting the association of black participants and weight regain, but did not reach statistical significance at  $p = .10$ . Findings regarding racial minorities and weight maintenance after a loss are inconsistent in the literature. Two large clinical trials examining weight loss and maintenance as a method of blood pressure control found that black participants tended to lose less weight initially, but then tended to regain less weight at 36 months (Kumanyika et al., 2002; Stevens et al., 2001). For example, in the Trials of Hypertension Prevention— Phase II, white participants lost 2.3 kg more weight than black participants at 6 months, but the difference in weight loss between Blacks and Whites was only 0.5 kg at 36 months (Stevens et al., 2001). In the Trial of Nonpharmacologic Interventions in the Elderly, weight regain between 6 months and the end of the trial was greater in white participants compared to black participants in both treatment arms (Kumanyika et al., 2002). Rickel and colleagues found that black persons lost less weight during the 6-month weight loss phase, but experienced a weight regain similar to their white counterparts during the 12-month maintenance phase (Rickel et al., 2007). Others have reported greater weight regain among black diabetic participants after a weight loss program (Wing & Anglin, 1996). Our

results lend support to the findings that weight regain after a behavioral weight loss trial is similar for white and black persons.

Barriers to healthy eating significantly predicted weight regain and unsuccessful weight maintenance in PREFER II. Perceived barriers to weight management have been reported by others (Andajani-Sutjahjo et al., 2004; Atlantis, Barnes, & Ball, 2008; Befort et al., 2007). The percentage of unsuccessful weight maintainers frequently experiencing the barriers of *healthy eating being too expensive* and *healthy eating being too time consuming* was higher compared to successful maintainers (7.5% vs. 0% and 19.0% vs. 8.8%, respectively) in a follow-up study of a university-based behavioral weight loss program (Befort et al., 2007). In line with these results, finding time for appropriate meal planning was difficult for a greater proportion of the unsuccessful maintainers compared to the successful maintainers in our study. Befort and colleagues also found that a higher percentage of unsuccessful maintainers (88.1%) reported frequently experiencing the barrier of *too easy to slip back into old habits* compared to successful maintainers (52.9%) (2007). This barrier could be perceived as a lack of motivation for sustaining weight management behaviors. Similarly, we found that a majority of the participants had difficulty with motivation for keeping off the weight and for eating appropriately. Others have reported in survey studies that a lack of time (Kearney & McElhone, 1999; Lappalainen, Saba, Holm, Mykkanen, Gibney et al., 1997; Reinli, Will, Thompson-Reid, Liburd, & Anderson, 1996) and lack of motivation (Andajani-Sutjahjo et al., 2004) were barriers to eating a healthy diet. Low motivation has also been reported as more common among regainers than maintainers in follow-up assessments of weight maintenance (DePue et al., 1995). The price of healthy food items has been reported to be a barrier to healthy eating (Andajani-Sutjahjo et al., 2004; Befort et al., 2007; Lappalainen et al., 1997). Yet, only 17% of participants

in PREFER II reported that the cost of low-fat/low-calorie foods was a *somewhat* or *very important* problem, perhaps because over half of the participants were in the highest income category ( $\geq$  \$50,000 annual household income).

Increasing age was protective against being an unsuccessful weight maintainer in one logistic regression model for PREFER II. This was not a consistent finding in other models, although age was included as a covariate in all the multivariate models. Yet, research findings support the association of weight loss maintenance with older age (Anderson, Vichitbandra, Qian, & Kryscio, 1999; Ogden, 2000), and the relationship of larger weight gain with younger age in a trial of weight gain prevention (Jeffery, McGuire, & French, 2002). The finding that increasing age was associated with successful maintenance could be a result of better adherence to behavior changes necessary for weight management. Older age has been associated with better medication adherence (Barclay, Hinkin, Castellon, Mason, Reinhard et al., 2007; Hinkin, Hardy, Mason, Castellon, Durvasula et al., 2004; O'Connell, Braitstein, Hogg, Yip, Craib et al., 2003; Sajatovic, Blow, Kales, Valenstein, Ganoczy et al., 2007), adherence to treatment for alcohol addiction (Oslin, Pettinati, & Volpicelli, 2002), as well as with better adherence to dietary and physical activity recommendations (Bautista-Castano, Molina-Cabrillana, Montoya-Alonso, & Serra-Majem, 2004), and higher attendance at weight loss treatment sessions (Clark, Niaura, King, & Pera, 1996).

The impact of a stressful event on eating habits significantly predicted weight regain in the subsample of participants who reported experiencing a stressful life event. Psychological stress results in a physiologic stimulation of the hypothalamic-pituitary-adrenal axis resulting in increases in glucocorticoids (including cortisol) and activation of the sympathetic nervous system, which causes an increase in blood pressure and heart rate (Black, 2006; Kyrou,

Chrousos, & Tsigos, 2006). Clinical evidence indicates that cortisol or additional glucocorticoids may be involved with higher levels of food intake (Bjorntorp, 2001), particularly appetizing, high-calorie “comfort” foods, in an effort to ameliorate the physiologic effects of stress (Dallman, Pecoraro, Akana, La Fleur, Gomez et al., 2003). Research suggests that individuals who are more physiologically responsive to stress are at higher risk of becoming obese and developing central adiposity (Bjorntorp, 2001; Brydon, Wright, O'Donnell, Zachary, Wardle et al., 2008). For example, abdominal obesity was associated with larger stress-related increases in diastolic blood pressure and total peripheral resistance in pre-menopausal women (Davis, Twamley, Hamilton, & Swan, 1999). Women who secreted more cortisol in response to stress ate more food between meals (Newman, O'Connor, & Conner, 2007) and more calorie-dense, sweet and high-fat foods (Epel, Lapidus, McEwen, & Brownell, 2001). Also, women with greater inflammatory cytokine responses to stress had greater central adiposity compared to those with lower cytokine stress responses (Brydon et al., 2008).

Stress has been linked to weight change in several studies (Brunner, Chandola, & Marmot, 2007; DePue et al., 1995; Sarlio-Lahteenkorva, Rissanen, & Kaprio, 2000; Steptoe & Wardle, 2005; Vgontzas, Lin, Papaliaga, Calhoun, Vela-Bueno et al., 2008); however, the change in weight is not always a gain. Individual responses to stress might also include decreased appetite and food intake (Dallman et al., 2003; Wardle & Gibson, 2002). While a long-term study in Finland found that men who regained weight reported higher stress levels than maintainers (Sarlio-Lahteenkorva et al., 2000), others have noted that the effect of work stress on weight was related to initial BMI. Individuals with high levels of work stress and a BMI  $< 22 \text{ kg/m}^2$  experienced weight loss at the 5-year assessment while stressed overweight and obese persons (BMI  $> 27 \text{ kg/m}^2$ ) gained weight (Kivimaki, Head, Ferrie, Shipley, Brunner et al.,



2006). In our study, a greater impact of a stressful event on eating habits was significantly related to weight gain among the 69 individuals who had experienced a stressful life event, but the percentage of time that stress influenced eating in the entire sample was not related to weight change. These findings could be because individuals who did not report a stressful event had lower levels of stress overall or perhaps had an individual physiologic response to stress that did not influence their eating behavior. The percentage of time that stress-reducing techniques were used was also not predictive of weight change, possibly because these techniques were used rather infrequently.

Some factors— self-efficacy, social support and low-fat diet experiences— were not associated with weight maintenance in this study despite being associated with weight management in previous studies (Elfhag & Rossner, 2005; Kayman et al., 1990; Wing & Jeffery, 1999; Wolfe, 2004). Yet, some have found that self-efficacy for weight management was not correlated with weight loss (Fontaine & Cheskin, 1997). In agreement with our findings, Linde et al. noted that while self-efficacy beliefs predicted weight loss during treatment, self-efficacy did not predict weight change during the post-treatment time frame (Linde et al., 2006). Self-efficacy for resisting eating, as measured by the WEL, changed modestly during PREFER II with a mean increase for the sample of 1.4%. Self-efficacy for exercise was unrelated to weight maintenance in our study perhaps because the SEE was originally developed for and tested in an older population (Resnick & Jenkins, 2000). Some items, e.g. how confident are you that you could exercise if the weather was bothering you or you felt pain when exercising, might not have been relevant to the PREFER II participants. SEE scores were also unremarkable with an average score of 5.4 on a scale of 0 to 10. The level of social support that participants reported in this study was relatively high at baseline (mean 26.5) and increased by only 4% at the follow-up

PREFER II assessment, which could account for the lack of a relationship between social support and weight change in this study. Additionally, a mean weight increase of 4.5% would not be expected to be associated with an increase in social support even though the increase was minimal. Regarding low-fat diet experiences, as measured by the ELF, participants had fairly positive experiences adhering to the low-fat diet at baseline of PREFER II and reported essentially no change in their experiences during the 18 months, which could account for the ELF scale being unrelated to weight maintenance in this study.

A few limitations to our study existed. Because this was a follow-up study of weight maintenance, the selection of participants was restricted to those who took part in the PREFER weight loss trial and the demographic characteristics of the participants were confined to that sample. Thus, the representation of black participants was somewhat limited and a sample of 26 black individuals (22% of the total sample) might not be considered large enough to draw conclusions about weight maintenance in this racial group. Larger studies with greater proportions of black participants are needed to confirm these findings. Over half of the black and white participants in the sample had a higher mean household income and education level than that of the county and state. Therefore, these findings might be generalizable to individuals of a higher socioeconomic status. In particular, because health disparities are often associated with a lower socioeconomic level (Lantz et al., 1998; Sorlie, Backlund, & Keller, 1995), it would be important to examine weight maintenance in a sample that was more diverse in terms of education and income. Because only the WEL was previously tested for validity and reliability in an African American population, the cultural salience of the other measures is not known. However, these scales have been used in samples with multiple racial groups without any obvious or known difficulties. Additionally, our sample consisted of only 15 males and only 1

black male. This small proportion of men would suggest that our findings may be generalizable only to women and the representation of one black male definitely prohibits generalizability to black men. Typically, men are underrepresented in weight loss and maintenance studies (Phelan, Hill, Lang, Dibello, & Wing, 2003; Tate, Jackvony, & Wing, 2003; Wing et al., 2006). Yet, some research suggests there may be differences in weight management between genders (Richelsen et al., 2007; Sarlio-Lahteenkorva et al., 2000). Recent findings revealed a significant increase in the prevalence of obesity among men (Ogden, Carroll, Curtin, McDowell, Tabak et al., 2006), reinforcing the need to examine weight maintenance in a larger sample of men.

The strengths of our study include a long-term follow-up assessment, an examination of weight maintenance among black individuals, an objective assessment of weight, and a high percentage of participants who completed the weight loss trial returned to participate in PREFER II. Maintenance of weight is not often examined for more than a year after a weight loss trial (Early et al., 2007; Fogelholm et al., 1999; Harvey-Berino, Pintauro, & Gold, 2002; LeCheminant et al., 2005). Thus, this study adds to the scant body of literature investigating long-term weight maintenance after weight loss treatment. Because of the financial and logistical constraints of assessing individuals' weights, weight maintenance studies frequently use self-reported weights (Befort et al., 2007; Lowe et al., 2001; McGuire, Wing, & Hill, 1999; Raynor et al., 2006). In our study, we weighted all but one participant using a calibrated digital scale, providing objective evidence of weight maintenance. Although previous investigations have found self-reported weights to be valid (Stunkard & Albaum, 1981), objective data assessment is more desirable. Our study also adds to the limited body of knowledge about weight maintenance in black individuals. Weight maintenance has rarely been studied in this population despite the fact that obesity is more prevalent among black persons (Ogden et al., 2006). Additionally, this

study provides support to the idea that maintenance of weight after a weight loss trial does not significantly differ for black persons compared to white persons and endorses the belief that strategies for maintaining weight need to be developed and disseminated to individuals of both racial groups. PREFER II had a very good return of participants after the weight loss trial with over 90% of individuals participating in this assessment of weight maintenance, and no differences existed between the few participants who returned and those who did not. The high participation rate of former PREFER participants reduces the likelihood that these findings are biased as a result of individuals who were less successful at weight maintenance not returning for the long-term study.

#### **4.6 CONCLUSION**

The results of this study indicate that a majority of the participants were able to maintain their weight 18 months after completing a behavioral weight loss program with a similar amount of weight change experienced by black and white participants. This study demonstrated that a focus on reducing barriers to weight management and healthy eating as well as coping with stressful life events is necessary to assist black and white persons with weight maintenance. Continued investigations need to determine the most appropriate strategies to help individuals reduce the negative impact of stress and overcome individual barriers they experience related to sustaining a their weight loss long-term.

**Table 4.1: Items Included in the Social Support Composite Variable**

<b>ELF</b>	<b>Strongly</b>			<b>Strongly</b>	
<i>Please indicate the extent to which this factor has made</i>	<b>Disagree</b>			<b>Agree</b>	
<i>it difficult for you to follow your eating plan:</i>	<b>1</b>	<b>2</b>	<b>3</b>	<b>4</b>	<b>5</b>
<ul style="list-style-type: none"> <li>Do you feel you are bothering your family members sometimes?</li> <li>Do you find that family members complain about the low-fat diet?</li> <li>Do you sometimes prepare separate meals for yourself and other family members?</li> <li>Do you find that your spouse/family discourages you from staying on a low-fat diet?</li> </ul>					
<b>BHE</b>	<b>Not at all a</b>			<b>Very important</b>	
<i>Please indicate the extent to which this factor has made</i>	<b>problem for</b>			<b>problem for</b>	
<i>it difficult for you to follow appropriate eating habits:</i>	<b>me</b>			<b>me</b>	
	<b>1</b>	<b>2</b>	<b>3</b>	<b>4</b>	<b>5</b>
<ul style="list-style-type: none"> <li>My family does not support my efforts to lose weight.</li> <li>When I am with my family I find it difficult to watch what I eat.</li> <li>My friends do not support me when I try to change my eating.</li> </ul>					

*Note.* ELF= Experiences Associated with Following a Low-Fat Diet Scale; BHE= Barriers to Healthy Eating Scale. Responses selected on a five-point scale.

**Table 4.2: Sociodemographic and Baseline Variables for PREFER II**

	Total	White	Black	Difference				
	( <i>N</i> = 107)	( <i>n</i> = 81)	( <i>n</i> = 26)	between groups				
Variable	<i>n</i> (%)	<i>n</i> (%)	<i>n</i> (%)	$\chi^2$	<i>p</i>			
<b>Gender</b>								
Female	92 (86.0)	67 (83.0)	25 (96.0)	0.05 <sup>c</sup>	.11			
Male	15 (14.0)	14 (17.0)	1 (4.0)					
<b>Marital status<sup>a</sup></b>								
Married/living with partner	75 (70.8)	63 (79.0)	12 (46.0)	10.08	<.01			
Not married/separated	31 (29.2)	17 (21.0)	14 (54.0)					
<b>Employment<sup>b</sup></b>								
Full time	83 (79.1)	59 (74.7)	24 (92.4)					
Part time	10 (9.5)	9 (11.4)	1 (3.8)	3.13 <sup>c</sup>	.21			
Other	12 (11.4)	11 (13.9)	1 (3.8)					
<b>Income<sup>a</sup></b>								
≤ \$30,000/yr	16 (15.1)	12 (15.0)	4 (15.4)					
\$30-50,000/yr	27 (25.2)	18 (22.5)	9 (34.6)	1.74 <sup>c</sup>	.44			
≥ \$50,000/yr	63 (58.9)	50 (62.5)	13 (50.0)					
	<i>Mean</i>	<i>SD</i>	<i>Mean</i>	<i>SD</i>	<i>Mean</i>	<i>SD</i>	<i>U</i>	<i>p</i>
	<i>Median</i>		<i>Median</i>		<i>Median</i>		<i>z</i>	
<b>Education</b> (years)	15.3	2.6	15.4	2.5	14.69	2.7	856.5	.15
(Range: 12-23)	16.0		16.0		14.5		-1.45	
<b>Age</b> (years)	46.3	6.9	46.1	7.1	46.8	6.4	1006.0	.73
(Range: 20-55)	48.0		48.0		48.5		-0.34	

	<b>Total</b>		<b>White</b>		<b>Black</b>		<b>Difference</b>	
	<b>(N = 107)</b>		<b>(n = 81)</b>		<b>(n = 26)</b>		<b>between</b>	
							<b>groups</b>	
<b>Variable</b>	<i>Mean</i>	<i>SD</i>	<i>Mean</i>	<i>SD</i>	<i>Mean</i>	<i>SD</i>	<i>U</i>	<i>p</i>
	<i>Median</i>		<i>Median</i>		<i>Median</i>		<i>z</i>	
<b>BHE<sup>b</sup></b>	52.0	15.1	51.0	15.3	55.1	14.4	843.5	.17
(Range: 22-110)	54.0		53.0		60.0		-1.36	
<b>ELF<sup>d</sup></b>	88.2	12.6	87.9	13.6	88.2	9.4	953.0	.65
(Range: 26-130)	87.0		87.0		89.5		-0.46	
<b>WEL<sup>b</sup></b>	119.8	35.3	120.8	35.9	116.6	34.1	939.5	.52
(Range: 0-180)	113.0		119.0		108.0		-0.65	
<b>Social support<sup>d</sup></b>	26.5	6.3	26.4	6.5	26.9	5.6	1017.5	.94
(Range: 7-35)	28.0		28.0		27.5		-0.02	
	<i>Mean</i>	<i>SD</i>	<i>Mean</i>	<i>SD</i>	<i>Mean</i>	<i>SD</i>	<i>t</i>	<i>p</i>
	<i>Median</i>		<i>Median</i>		<i>Median</i>			
<b>Weight (lbs)</b>	193.9	33.3	191.7	33.5	200.7	32.4	-1.20	.23
(Range: 126.7-264.4)	192.9		192.0		199.1			

*Note.* ELF= Experiences Associated with Following a Low-Fat Diet Scale; BHE= Barriers to Healthy Eating Scale; WEL= Weight Efficacy Lifestyle Scale; SD= Standard deviation; U= Mann Whitney U; t= t-value p= p-value; z= z-value. <sup>a</sup>One white participant had missing data. <sup>b</sup>Two white participants had missing data. <sup>c</sup>Fisher's exact test. <sup>d</sup>Three white participants had missing data.

**Table 4.3: PREFER II Study Variables for the Total Sample, Black and White Participants**

	Total		White		Black		Difference		
	(N = 107)		(n = 81)		(n = 26)		between groups		
Variable	n (%)		n (%)		n (%)		$\chi^2$	p	
Successful maintenance									
(≤ 5% weight regain)	61 (57.0)		47 (58.0)		14 (53.8)				
Unsuccessful maintenance								0.14	.71
(>5% weight regain)	46 (43.0)		34 (42.0)		12 (46.2)				
	Mean	SD	Mean	SD	Mean	SD			
	Median		Median		Median		t	p	
% Weight change	4.6	5.8	4.4	5.6	5.0	6.6	-0.45	.65	
(Range: -14.81-27.02)	4.2		4.2		4.2				
% ELF change <sup>a</sup>	.65	11.5	-.37	10.9	3.72	12.8	-1.58	.12	
(Range: -28.4-37.7)	0		-1.59		5.34				
SEE <sup>b</sup>	5.4	2.5	5.4	2.6	5.3	2.5	0.14	.89	
(Range: 0-10)	5.7		5.8		4.7				
	Mean	SD	Mean	SD	Mean	SD	U	p	
	Median		Median		Median		z		
% BHE change <sup>c</sup>	12.7	30.5	13.1	29.7	11.5	33.5	1003.0	.86	
(Range: -55.7-125.8)	8.5		8.5		7.6		-0.18		
% WEL change <sup>c</sup>	1.4	42.8	.62	44.5	3.6	38.1	938.0	.51	
(Range: -56.2-261.9)	-5.0		-6.3		-2.7		-0.66		
% Social support change <sup>a</sup>	3.9	23.9	4.7	24.7	1.6	21.8	956.0	.66	
(Range: -44.0-100.0)	0		0		0		-0.44		



	<b>Total</b>		<b>White</b>		<b>Black</b>		<b>Difference</b>	
	<b>(N = 107)</b>		<b>(n = 81)</b>		<b>(n = 26)</b>		<b>between</b>	
							<b>groups</b>	
<b>Variable</b>	<i>Mean</i>	<i>SD</i>	<i>Mean</i>	<i>SD</i>	<i>Mean</i>	<i>SD</i>	<i>U</i>	<i>p</i>
	<i>Median</i>		<i>Median</i>		<i>Median</i>		<i>z</i>	
<b>How often (% of time) does stress influence how you eat?<sup>b,d</sup></b>	56.8	30.7	57.9	28.9	53.5	36.0	970.5	.61
	50.0		70.0		60.0		-0.51	
(Range: 0-100)								
<b>How often (% of time) did you use tricks to lower your stress level?<sup>b,d</sup></b>	38.7	28.5	38.9	27.7	38.1	31.2	1004.5	.79
	35.0		35.0		35.0		-0.26	
(Range: 0-100)								
<b>How much did this stressful event affect your eating habits?<sup>b,e</sup></b>	7.0	3.1	7.0	2.9	7.2	3.5	433.5	.45
	8.0		8.0		8.5		-0.76	
(Range: 0-10)								

*Note.* ELF= Experiences Associated with Following a Low-Fat Diet Scale; SEE= Self-Efficacy for Exercise Scale; BHE= Barriers to Healthy Eating Scale; WEL= Weight Efficacy Lifestyle Scale; SD= Standard deviation; U= Mann Whitney U; t= t-value p= p-value; z= z-value. <sup>a</sup>Three white participants had missing baseline data. <sup>b</sup>Only measured in PREFER II; therefore, no percent change score presented. <sup>c</sup>Two white participants had missing baseline data. <sup>d</sup>One white participant had missing data. <sup>e</sup>Subsample analysis of n=69 with White n=49, Black n=20.

**Table 4.4: Multivariate Linear Regression of Race Predicting % Weight Change (N=106, White n=80, Black n=26)**

<i>Variable</i>	<i>b</i>	<i>SE (b)</i>	<i>Standardized Beta</i>	<i>t-value</i>	<i>p-value</i>
Age	-0.06	0.09	-.08	-0.73	.47
Gender <sup>a</sup>	-2.50	1.83	-.15	-1.37	.17
Marital status <sup>b</sup>	1.62	1.43	.13	1.13	.26
Education	0.16	0.25	.07	0.66	.51
Income <sup>c</sup>					
≤ \$30,000/yr	-1.20	1.86	-.07	-0.64	.52
\$30-50,000/yr	0.81	1.46	.06	0.55	.58
Race <sup>d,e</sup>					
(Black/White)	0.86	1.45	.06	0.60	.55

*Note.* One participant was excluded from the model due to missing data on marital status and income. <sup>a</sup>Female coded as 0 and treated as the reference. <sup>b</sup>Not married/separated coded as 0 and treated as the reference. <sup>c</sup>Compared to the reference group, ≥ 50,000. <sup>d</sup>White participants coded as 0 and treated as the reference. <sup>e</sup>The unadjusted effect for race was non-significant,  $b = 0.59$ ,  $SE = 1.31$ ,  $p = .65$ .

**Table 4.5: Multivariate Logistic Regression of Race Predicting Unsuccessful Weight Maintenance (N=106, White n=80, Black, n=26)**

<i>Variable</i>	<i>b</i>	<i>SE (b)</i>	<i>Wald</i>	<i>df</i>	<i>p-value</i>	<i>Odds Ratio (OR)</i>	<i>95% CI for OR</i>
Age	-0.05	0.03	2.07	1	.15	.95	.89-1.02
Gender <sup>a</sup>	-0.93	0.68	1.85	1	.17	.39	.10-1.51
Marital status <sup>b</sup>	0.58	0.52	1.24	1	.26	1.79	.64-4.98
Education	0.04	0.09	0.16	1	.69	1.04	.87-1.24
Income <sup>c</sup>							
≤ \$30,000/yr	-0.57	0.67	0.73	1	.39	.56	.15-2.08
\$30-50,000/yr	-0.25	0.51	0.23	1	.63	.78	.29-2.14
Race <sup>d,e</sup>							
(Black/White)	0.32	0.51	0.39	1	.53	1.38	.51-3.77

*Note.* Unsuccessful weight maintenance defined as > 5% regain. One participant was excluded from the model due to missing data on marital status and income. <sup>a</sup>Female coded as 0 and treated as the reference. <sup>b</sup>Not married/separated coded as 0 and treated as the reference. <sup>c</sup>Compared to the reference group, ≥ 50,000. <sup>d</sup>White participants coded as 0 and treated as the reference. <sup>e</sup>The unadjusted effect for race was non-significant, Odds Ratio = 1.18, 95% Confidence Interval = 0.49-2.88,  $p = .71$ .

**Table 4.6: Multivariate Linear Analysis with ELF Change, BHE Change, and WEL Change Predicting % Weight Change (N=101, White n=76, Black n=25)**

<i>Variable</i>	<i>b</i>	<i>SE (b)</i>	<i>Standardized Beta</i>	<i>t-value</i>	<i>p-value</i>
Age	-0.13	0.08	-.15	-1.50	.13
Gender <sup>a</sup>	-0.57	1.84	-.03	-0.31	.75
Marital status <sup>b</sup>	2.35	1.41	.18	1.67	.09
Education	0.04	0.25	.02	0.16	.87
Income <sup>c</sup>					
≤ \$30,000/yr	-0.65	1.86	-.04	-0.35	.72
\$30-50,000/yr	0.46	1.38	.03	0.33	.73
% ELF change	-0.07	0.05	-.15	-1.42	.15
% BHE change	0.08	0.02	.35	3.21	<.01
% WEL change	-0.01	0.02	-.07	-0.66	.51
Race <sup>d</sup>					
(Black/White)	2.33	1.41	.17	1.65	.10

*Note.* Three participants excluded from the model due to missing data on marital status and income or questionnaires at baseline. Three participants who were influential outliers excluded from the model. BHE= Barriers to Healthy Eating Scale; WEL= Weight Efficacy Lifestyle Scale; ELF= Experiences Associated with Following a Low-Fat Diet Scale. <sup>a</sup>Female coded as 0 and treated as the reference. <sup>b</sup>Not married/separated coded as 0 and treated as the reference. <sup>c</sup>Compared to the reference group, ≥ \$50,000. <sup>d</sup>White participants coded as 0 and treated as the reference.

**Table 4.7: Top Five Barriers to Healthy Eating: % of Participants who Selected “Somewhat” or “Very” Important Problem for me**

<i>Barrier</i>	<i>Total Sample</i>	<i>Successful</i>	<i>Unsuccessful</i>	<i>White</i>	<i>Black</i>
	<i>(N = 107)</i>	<i>(n = 61)</i>	<i>(n = 46)</i>	<i>(n = 81)</i>	<i>(n = 26)</i>
1. Losing weight is rewarding, but I have trouble staying motivated to keep off the weight I lost.	65.6%	65.2%	66.0%	66.7%	69.2%
2. When I am very hungry, I have trouble controlling what I eat.	63.8%	60.6%	68.0%	65.4%	69.2%
3. It is difficult to motivate myself to eat appropriately.	49.1%	51.2%	46.0%	50.6%	57.7%
4. It is difficult to find time to plan appropriate meals for myself.	44.8%	39.4%	52.0%	44.5%	50.0%
5. I use food as a reward or treat for myself.	44.8%	41.0%	<sup>a</sup>	49.4%	<sup>a</sup>
5. Resisting tempting high fat/high calorie foods in my work setting is difficult.	<sup>b</sup>	<sup>b</sup>	50.0%	<sup>b</sup>	50.0%

<sup>a</sup>The fifth barrier for the unsuccessful and black groups was *Resisting tempting high fat/high calorie foods in my work setting is difficult*. <sup>b</sup>The fifth barrier for the total sample, successful, and white groups was *I use food as a reward or treat for myself*.

**Table 4.8: Multivariate Logistic Regression with the Linear and the Quadratic Effect for BHE Change, ELF Change and WEL Change Predicting Unsuccessful Weight Maintenance with Two Outlying Values (N=103, White n=77, Black n=26)**

<i>Variable</i>	<i>b</i>	<i>SE (b)</i>	<i>Wald</i>	<i>df</i>	<i>p-value</i>	<i>Odds Ratio</i> <i>(OR)</i>	<i>95% CI</i> <i>for OR</i>
Age	-0.09	0.04	5.42	1	.02	0.91	.85-.99
Gender <sup>a</sup>	-0.56	0.79	0.50	1	.47	0.57	.12-2.71
Marital status <sup>b</sup>	0.94	0.64	2.18	1	.14	2.56	.73-8.91
Education	0.01	0.10	<0.01	1	.92	1.01	.83-1.23
Income <sup>c</sup>							
≤ \$30,000/yr	-0.66	0.80	0.69	1	.40	0.51	.11-2.47
\$30-50,000/yr	-0.72	0.62	1.35	1	.24	0.49	.15-1.63
% ELF change	-0.05	0.02	3.66	1	.05	0.95	.91-1.001
% BHE change	0.04	0.01	8.57	1	<.01	1.04	1.01-1.07
% WEL change	<0.01	<0.01	0.09	1	.76	1.00	.99-1.02
Quadratic effect for % BHE change	<0.01	<0.01	7.24	1	<.01	~1.00	.9991-.9998
Race <sup>d</sup>							
(Black/White)	1.03	0.62	2.76	1	.09	2.80	.83-9.46

*Note.* Unsuccessful weight maintenance defined as > 5% regain. Three participants excluded

from the model due to missing data on marital status and income or questionnaires at baseline.

One participant excluded from the model who was an influential outlier on WEL change. BHE=

Barriers to Healthy Eating Scale; WEL= Weight Efficacy Lifestyle Scale; ELF= Experiences

Associated with Following a Low-Fat Diet Scale. <sup>a</sup>Female coded as 0 and treated as the

reference. <sup>b</sup>Not married/separate coded as 0 and treated as the reference. <sup>c</sup>Compared to the

reference group, ≥ \$50,000. <sup>d</sup>White participants coded as 0 and treated as the reference.

**Table 4.9: Multivariate Logistic Regression with the Linear and the Quadratic Effect for BHE Change, ELF Change, and WEL Change Predicting Unsuccessful Weight Maintenance Without Two Outlying Values (N=101, White n=76, Black n=25)**

<i>Variable</i>	<i>b</i>	<i>SE (b)</i>	<i>Wald</i>	<i>df</i>	<i>p-value</i>	<i>Odds Ratio</i> <i>(OR)</i>	<i>95% CI</i> <i>for OR</i>
Age	-0.10	0.040	7.10	1	<.01	0.90	0.83-.97
Gender <sup>a</sup>	-0.32	0.862	0.14	1	.70	0.72	0.13-3.91
Marital status <sup>b</sup>	1.26	0.678	3.47	1	.06	3.53	0.94-13.34
Education	0.03	0.104	0.11	1	.74	0.97	0.79-1.18
Income <sup>c</sup>							
≤ \$30,000/yr	-0.68	0.807	0.70	1	.40	0.51	0.10-2.47
\$30-50,000/yr	-0.81	0.625	1.69	1	.19	0.44	0.13-1.51
% ELF change	-0.04	0.024	2.94	1	.08	0.96	0.91-1.00
% BHE change	0.04	0.014	9.60	1	<.01	1.04	1.02-1.07
% WEL change	<0.01	<0.01	0.14	1	.71	1.00	0.99-1.02
Quadratic effect for % BHE change	<0.01	<0.01	0.38	1	.53	1.00	0.99-1.00
Race <sup>d</sup>							
(Black/White)	1.34	.66	4.05	1	.04	3.81	1.04-14.06

*Note.* Unsuccessful weight maintenance defined as > 5% regain. Three participants excluded from the model due to missing data on marital status and income or baseline questionnaires.

Three participants excluded from the model who were influential outliers (one on WEL change, two on BHE change). BHE= Barriers to Healthy Eating Scale; WEL= Weight Efficacy Lifestyle Scale; ELF= Experiences Associated with Following a Low-Fat Diet Scale. <sup>a</sup>Female coded as 0 and treated as reference. <sup>b</sup>Not married/separated coded as 0 and treated as reference. <sup>c</sup>Compared to the reference group, ≥ \$50,000. <sup>d</sup>Whites coded as 0 and treated as the reference.

**Table 4.10: Multivariate Linear Regression of % Weight Change Predicted by how Stressful Event Affected Eating on a Scale of 0 (No Effect) to 10 (Most Effect), (n=68, White n=48, Black n=20)**

<i>Variable</i>	<i>b</i>	<i>SE (b)</i>	<i>Standardized Beta</i>	<i>t-value</i>	<i>p-value</i>
Age	-0.03	0.10	-.04	-0.34	.73
Gender <sup>a</sup>	-2.73	2.33	-.16	-1.17	.24
Marital status <sup>b</sup>	3.13	1.80	.25	1.73	.08
Education	0.29	0.32	.13	0.91	.36
Income <sup>c</sup>					
≤ \$30,000/yr	-0.23	2.17	-.01	-0.11	.91
\$30-50,000/yr	2.41	1.93	.17	1.25	.21
Effect of stressful life event on eating (0-10)	0.51	0.24	.26	2.11	.04
Race <sup>d</sup> (Black/White)	-1.02	1.82	-.08	-0.56	.57

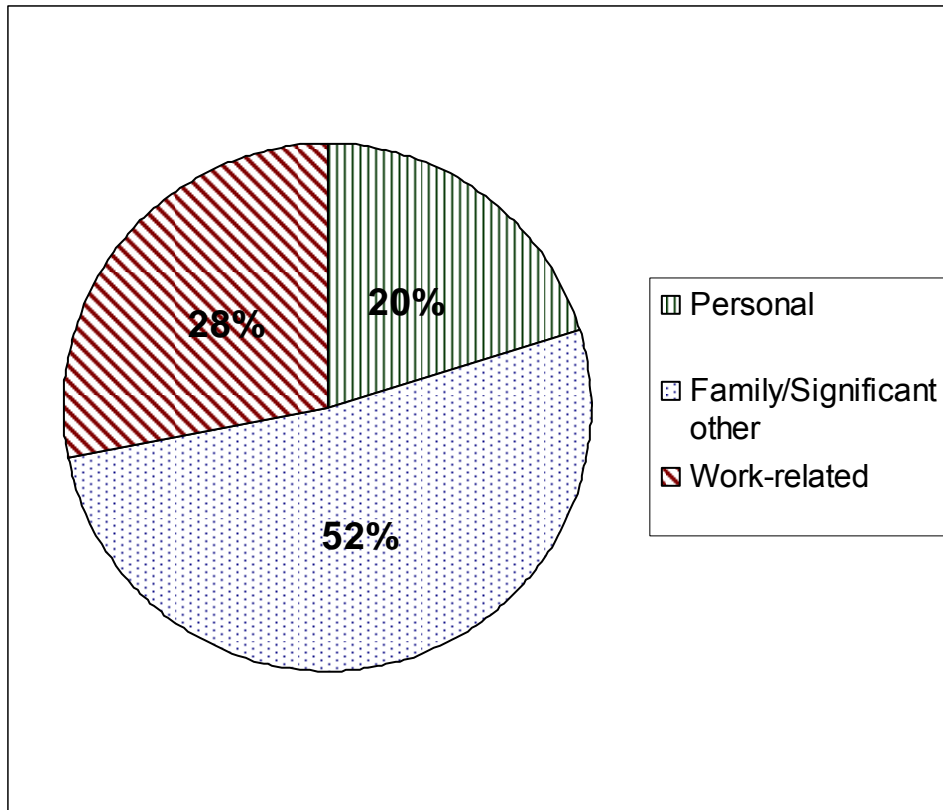
*Note.* Model includes only the subsample of participants who reported experiencing a stressful event. <sup>a</sup>Female coded as 0 and treated as the reference. <sup>b</sup>Not married/separated coded as 0 and treated as the reference. <sup>c</sup>Compared to the reference group, ≥ \$50,000. <sup>d</sup>White participants coded as 0 and treated as the reference.



**Table 4.11: Multivariate Logistic Regression of Unsuccessful Weight Maintenance Predicted by how the Stressful Event Affected Eating on a Scale of 0 (No Effect) to 10 (Most Effect), (n=68, White n=48, Black n=20)**

<i>Variable</i>	<i>b</i>	<i>SE (b)</i>	<i>Wald</i>	<i>df</i>	<i>p-value</i>	<i>Odds Ratio</i> <i>(OR)</i>	<i>95% CI</i> <i>for OR</i>
Age	-0.03	0.04	0.43	1	.51	0.97	0.90-1.05
Gender <sup>a</sup>	-0.82	0.90	0.83	1	.36	0.44	0.07-2.56
Marital status <sup>b</sup>	0.83	0.70	1.42	1	.23	2.31	0.58-9.09
Education	0.13	0.12	1.31	1	.25	1.14	0.91-1.44
Income <sup>c</sup>							
≤ \$30,000/yr	-0.57	0.83	0.47	1	.49	0.57	0.11-2.87
\$30-50,000/yr	0.17	0.72	0.05	1	.81	1.18	0.29-4.86
Effect of stressful life event on eating (0-10)	0.26	0.11	5.37	1	.02	1.30	1.04-1.63
Race <sup>d</sup>							
(Black/White)	-0.42	0.66	0.39	1	.53	0.66	0.18-2.42

*Note.* Unsuccessful weight maintenance defined as > 5% regain. Model includes only the subsample of participants who reported experiencing a stressful event. <sup>a</sup>Female coded as 0 and treated as the reference. <sup>b</sup>Not married/separated coded as 0 and treated as the reference. <sup>c</sup>Compared to the reference group, ≥ \$50,000. <sup>d</sup>White participants coded as 0 and treated as the reference.



**Figure 4.1: Stressful Life Event Categories**

## 5.0 RESULTS MANUSCRIPT #2

### Use of Behavioral Strategies for Weight Maintenance 18 Months After a Behavioral Weight Loss Trial

#### 5.1 ABSTRACT

**Objective:** To examine the behavioral strategies used by participants for weight maintenance after a behavioral weight loss trial and investigate whether or not differences in strategy use existed between black and white participants as well as between successful and unsuccessful weight maintainers. **Methods:** We conducted an ancillary study, PREFER II, 18 months after the completion of a behavioral weight loss trial, PREFER. Participants self-identified their race as Black or White. We weighed participants wearing light clothing and no shoes using the Tanita digital scale and asked about the percentage of time in the previous 18 months individuals used 16 strategies they learned during PREFER. Successful weight maintenance was defined as  $\leq 5\%$  weight regain. **Results:** The sample ( $N = 107$ ,  $n = 81$  White,  $n = 26$  Black) was predominantly female (86.0%), middle-aged ( $M = 46.3$ ,  $SD = 6.9$  years old), and successful at weight maintenance. Only 25% of the 16 behavioral strategies were used more than half the time. Reading food labels while grocery shopping was the most commonly used strategy for all participants. Two differences in strategy use were found between the black and white

participants; black participants used recipe modification and portion-control methods less often than white participants,  $ps < .04$ . There were no differences in strategy use between the successful and unsuccessful participants. **Conclusions:** Individuals who participated in a behavioral weight loss trial did not use most weight-control strategies they had learned for the majority of time in the 18 months after the trial. Some differences between racial groups suggest the incorporation of culturally-tailored strategies in weight management programs to support the weight-maintenance efforts of black individuals.

## 5.2 INTRODUCTION

Obesity and overweight are global problems that affect the health of millions of individuals in the United States and worldwide (Roth et al., 2004). Additionally, black persons are affected in greater proportions by obesity and its concomitant health conditions (Must et al., 1999; Ogden et al., 2006). One of the utmost challenges in the area of obesity treatment is the dilemma of weight regain after loss (Jeffery et al., 2000). Modifications of eating and physical activity lifestyle behaviors remain the features of effective weight loss treatment, but are difficult to implement long-term (Cummings, Parham, Strain, & American Dietetic Association, 2002). Little is known about the strategies individuals continue to use after behavioral weight loss treatment to promote weight maintenance, or if differences exist between racial minority groups in their use of weight maintenance strategies.

Empirical evidence from The National Weight Control Registry, a registry of individuals who have been able to lose at least 13.6 kg and maintain the loss for a minimum of 1 year (Klem et al., 1997), supports the use of several behavioral strategies for successful weight maintenance,

e.g. increased physical activity, eating a low-fat diet, regularly self-monitoring food intake and body weight (Wing & Hill, 2001), restricting one's assortment of foods (Raynor et al., 2005), following a consistent weekly meal plan (Gorin et al., 2004) and eating breakfast (Wyatt et al., 2002). However, this registry has nearly all white participants (Wing & Phelan, 2005). Scant research has examined weight management strategies among black persons, but some findings suggest there may be differences in weight-control techniques used by black individuals. Tyler and colleagues found that African American women used more commercial diet tools and took part in weight loss behaviors for less time than white women who weighed less; African American women in this study reported discontinuing weight loss activities due to boredom, difficulty eating bland food, and lack of family support (Tyler, Allan, & Alcozer, 1997). Less time spent participating in weight loss behaviors may signify a problem for successful long-term weight maintenance. Cultural differences in food and eating preferences exist for some members of racial groups (Kumanyika, Morssink, & Agurs, 1992), such as food practices that are handed down from generation to generation or deep frying as a means of food preparation (Airhihenbuwa et al., 1996), and could add an additional barrier to efforts to sustain behavioral strategies for weight maintenance.

Successful weight maintenance seems to require ongoing adherence to the behavioral lifestyle changes from which the initial weight loss resulted (Perri & Foreyt, 2004). Therefore, the purpose of this investigation, PREFER II, was to examine the use of behavioral strategies for long-term weight maintenance 18 months after a behavioral weight loss trial to assess how frequently participants practiced strategies learned during the trial. We also explored whether or not differences existed in the use of behavioral weight-management strategies between black and

white participants as well as between successful weight maintainers and unsuccessful weight maintainers.

### **5.3 METHODS**

PREFER II was a descriptive, ancillary study conducted 18 months after the completion of PREFER, a randomized clinical trial of behavioral weight loss treatment. Recruitment for PREFER took place in three cohorts and participants were randomly assigned first to receive their preferred dietary treatment or not (Preference-Yes or Preference-No) and secondly to a standard reduced-calorie and fat diet or a lacto-ovo-vegetarian reduced-calorie and fat diet. The PREFER intervention used standard behavioral therapy (SBT) for weight loss, an established method that integrates instruction and counseling in modifying lifestyle behaviors, adjusting food intake to reduce calories and fat, and increasing physical activity (Wadden et al., 2004; Wing, 2004). Features of SBT include providing nutritional information, designating goals for daily dietary intake and weekly physical activity, presenting planned lessons to groups of 10-20 participants and facilitating group discussion. Participants also self-monitor food intake and physical activity, receive written interventionist feedback, and apply various behavioral change strategies shown to be effective, e.g. modifying one's environment, problem-solving, altering 'all or nothing' thinking and preventing relapse (Stunkard & Berthold, 1985; Wadden & Butryn, 2003; Wing, 1998). PREFER participants attended weekly group meetings during months 1-6, biweekly meetings in months 7-9 and monthly meetings during months 10-12. In the final 6-month maintenance phase of the trial, there were no group sessions and participants were not in contact with study personnel except to set up an end-of-study assessment appointment.

Further information about the design and findings of the PREFER trial have been published elsewhere (Burke, Choo et al., 2006; Burke et al., 2007; Burke, Styn et al., 2006; Burke, Warziski et al., 2008). Overall, the mean weight loss at trial end was between 4% and 8% for the four randomized groups with no significant difference in weight loss for persons in the lacto-ovo-vegetarian diet groups compared to the standard diet groups; individuals randomly assigned to Preference-No lost more weight than those who were randomized to Preference-Yes (Burke, Warziski et al., 2008).

For PREFER II, we mailed letters to participants asking them to return for a follow-up study 18 months after the PREFER trial ended. If participants did not respond by two weeks after the letter was sent, we called individuals on the phone to request that they return for one additional assessment. PREFER personnel had not informed participants during the trial that any follow-up study would occur, and there was no contact with participants after PREFER until the letter was sent asking for their participation in PREFER II. We collected information on current weight and behavioral strategies utilized for weight maintenance at the Clinical Translational Research Center or the School of Nursing at the University of Pittsburgh or another participant-selected convenient location, e.g., their workplace or home.

The eligibility criteria of the PREFER trial determined the inclusion and exclusion criteria of PREFER II. Participants were 18-55 years old when they were enrolled in PREFER, agreed to be randomized to receive their preferred treatment or not and one of the two dietary plans, had a BMI between 27 and 43 kg/m<sup>2</sup> inclusively, and had completed a 5-day food diary demonstrating they could self-monitor their eating. Exclusion criteria consisted of a medical diagnosis that required physician management of the diet or physical activity (e.g. diabetes, recent myocardial infarction), physical limitations affecting the ability to exercise, pregnancy or

planning a pregnancy during the trial, treatment for a psychological illness, reported daily consumption of four or more alcoholic drinks, current weight loss medication use or current/recent (within the past 6 months) enrollment in a weight loss program, or no regular consumption of meat, fish or poultry. The PREFER final assessment time point was the baseline of PREFER II; therefore, participants needed to have completed this visit to be eligible for PREFER II. Of the 132 PREFER participants from three cohorts who completed the weight loss trial, 119 took part in PREFER II between February 2006 and April 2007. Of the 119 who returned, two women were pregnant and one individual revealed that she had developed a binge eating disorder. Persons whose score on the Binge Eating Scale was  $> 37$ , suggesting they may have disordered eating behaviors (Gormally et al., 1982), were excluded from PREFER. Thus, these three individuals were excluded from PREFER II because they were not representative of the population from which the sample was to be drawn. In addition, nine participants self-selected a race other than Black or African American or White (three Hispanic, three Asian, one Native Hawaiian or other Pacific Islander, one Alaska Native and one American Indian) and were not included in the analysis. Hence, the total sample consisted of 107 individuals, 81 white participants and 26 black participants.

### **5.3.1 Measures**

We used the Tanita Digital Scale to measure weight in pounds with participants in light clothing and no shoes. For one out-of-state participant, we obtained a self-reported current weight, as prior studies have documented the validity of self-reported weights (Kuczmarski et al., 2001; Spencer et al., 2002). A 2-kg correction was added to this weight to account for potential under-



reporting, as has been done previously (Kramer et al., 1986; Linde, Jeffery et al., 2004; Palta et al., 1982).

We developed a survey for PREFER II in order to assess the amount of time since the completion of PREFER that participants utilized various behavioral strategies for weight maintenance. The survey asked the participant to select what percent of the time in the previous 18 months, on a scale of 0-100%, he/she used 16 different behavioral strategies that were a part of the PREFER trial's intervention sessions. Using four additional items, we asked about stressful life events and the relationship of stress to eating; these findings were reported previously (See Results Manuscript 1). This survey was pilot tested prior to administration in PREFER II with a group of women being counseled for weight loss who reported that it was easy to understand and complete. Excellent internal consistency for the survey was found with Cronbach's  $\alpha = .93$ .

We inquired about the use of several behavioral strategies in the survey. During the PREFER trial, participants learned how to self-monitor their food intake and physical activity each day in a paper diary, including the calories and fat grams of everything eaten as well as the total minutes and type of physical activity performed. The purpose of self-monitoring was to increase the participant's awareness of eating and activity behaviors in order to encourage behavior change. The effects of self-monitoring on weight management have been well documented (Baker & Kirschenbaum, 1993; Boutelle, Kirschenbaum, Baker, & Mitchell, 1999; Burke, Sereika, Music, Warziski, Styn et al., 2008; Wadden, Berkowitz, Womble, Sarwer, Phelan et al., 2005). Increasing daily lifestyle activity to enhance caloric expenditure was promoted, and participants learned ways to fit more activity into the day e.g., take the stairs instead of elevators, park the car farther away from the entrance, exit the bus one stop earlier and

walk the rest of the distance. Interventionists instructed participants to schedule time during the day for regular exercise, i.e. any aerobic exercise activity that increased the heart rate for at least 10 minutes, like brisk walking, bicycling or aerobics, and to increase their minutes of exercise to at least 150 minutes per week. Using positive reminders for participating in physical activity was also taught to participants, e.g. keeping gym shoes or bag in sight, making routine plans to exercise with a friend.

Participants learned about portion sizes and portion control as a means of reducing and managing caloric intake. They were given a reference card for determining the size of food items, e.g. one cup of cereal flakes is approximately the size of one's fist or three ounces of meat, fish or poultry is the size of a deck of cards. Another technique participants learned was how to read food labels paying particular attention to calorie and fat gram content for each serving, noting that packages may contain more than one serving per package. How to modify recipes so that the prepared food is lower in calories and fat grams was a part of the group sessions. Participants also learned to identify ingredients that may be high in fat or sugar and consider eliminating the ingredient, decreasing the amount or substituting a lower calorie or lower fat ingredient.

Knowing that one's environment can contribute significantly to weight management, interventionists taught participants to handle cues in their surroundings that may promote unhealthy eating or activity behaviors, e.g. keeping high-fat or high-calorie foods out of one's home and workplace or limiting television and computer time. Learning how to be assertive with others regarding following a healthy eating and activity plan was a part of the PREFER intervention, i.e. informing others in an honest, straightforward manner that one is committed to eating low-fat meals and exercising. The five steps of problem-solving— identify the problem,

brainstorm options for action, choose an action, make a plan to enact the action, take action and evaluate the results (D'Zurilla & Goldfried, 1971)— were part of the PREFER intervention sessions to help individuals successfully navigate challenging situations, e.g. how to manage eating at a social event or restaurant. How to eliminate negative thoughts, e.g. ‘all-or-nothing’ thinking about weight control or pessimism and excuse-making, was a component of the intervention. Participants learned how to confront negative thoughts and replace them with more positive, balanced thoughts like “I am not either on or off my diet; I am following a healthy eating lifestyle.” Participants were taught how to develop and utilize social support, including informational, practical and emotional support, during the PREFER trial and learned specific ways to encourage others to be supportive of weight control efforts, e.g. don’t offer second helpings of food, take part in physical activity together. As part of the PREFER trial’s component on weight maintenance, participants learned the importance of monitoring their weight and weighing themselves at least once a week in order to allow them to take preventive actions against weight gain. If participants gained more than two pounds, they were to enact the ‘restart plan’ they had established for themselves, e.g. recording food intake and activity again, making exercise a priority, continuing to weight oneself, choosing low-fat, healthy foods.

### **5.3.2 Statistical analysis**

Descriptive statistics were calculated for the percentage of the time over the 18-month period that each behavioral strategy was used. We stratified the total sample (by Blacks, Whites, successful participants, unsuccessful participants as well as successful and unsuccessful within each racial group) and presented descriptive statistics (means, standard deviations) for each strategy. In order to investigate if there were differences in behavioral strategy use between

successful and unsuccessful weight maintainers, we examined weight data from the final PREFER assessment (considered the baseline assessment for PREFER II) and the 18-month follow-up, PREFER II. We calculated a percent change score for weight as:

$$\frac{PREFER\ II\ weight - PREFER\ trial\ completion\ weight}{PREFER\ trial\ completion\ weight} \times 100 = \% \Delta\ weight\ (weight\ change)$$

We dichotomized this variable to derive two groups: successful weight maintainers ( $\leq 5\%$  weight regain) and unsuccessful weight maintainers ( $> 5\%$  weight regain). To test for differences in the use of each strategy between black and white participants, successful and unsuccessful participants, and successful and unsuccessful participants within and between each racial group, *t*-tests were used for normally distributed variables and the nonparametric Mann-Whitney U was used for non-normally distributed variables. We examined sociodemographic variables and baseline weight for differences between black and white participants as well as between those who returned for PREFER II and those who did not return using chi-square tests of independence, Fisher's exact tests, *t*-tests or Mann Whitney U tests as appropriate. We set the significance level for two-sided hypothesis testing at .05 and used SPSS (version 15.0, SPSS Inc., Chicago, IL 2006) for the analysis.

## 5.4 RESULTS

Sociodemographic and baseline characteristics of the PREFER II sample are found in Table 5.1. Most participants were female (86%), employed full time (79.1%) and middle-aged ( $M = 46.3$  years,  $SD = 6.9$  years). With the exception of marital status, black and white participants did not significantly differ on sociodemographic variables. There was also no difference in baseline

weight between racial groups,  $ps > .17$ . Sixty-one participants (57%) were successful weight maintainers and 46 (43%) were unsuccessful. In comparing the successful and unsuccessful weight maintainers, those who successfully maintained their weight weighed significantly more at baseline than those who did not ( $M = 201.2$  lbs,  $SD = 30.8$  lbs vs.  $M = 184.2$  lbs,  $SD = 34.2$  lbs, respectively,  $t_{(105)} = 2.69$ ,  $p = .008$ ). Individuals who did not return for PREFER II were not significantly different in sociodemographic variables (age, gender, race/ethnicity, education, income, marital status) or baseline weight compared to those who participated in PREFER II,  $ps > .08$ , supporting the generalizability of these findings to the entire PREFER sample. There were also no differences in the above variables between the nine individuals who self-selected a race other than Black or White and those included in the analysis,  $ps > .15$ .

The 16 strategies for the total sample, black, white, successful and unsuccessful participants are listed in Table 5.2 ordered from the highest mean percentage of the time to the lowest mean percentage of the time strategies were used by the total sample. Notably, approximately three-quarters of the behavioral strategies learned during PREFER, about which we inquired, were used less than half the time during the 18-month follow-up period. In fact, white, successful, and unsuccessful participants used only four strategies for more than a mean of 50% of the time, while black participants used three strategies for over half the time. The behavioral strategy used for the highest mean percentage of the time by the total sample as well as all the groups was *reading food labels while grocery shopping, looking at total calories, fat grams, and healthy claims ('reduced fat, low-cal, light')*. The mean percentage of the time this strategy was used was over 61% for all groups (see Table 5.2), and 58% of the total sample reported reading food labels 70% of the time or more. *Feeling you had the support of family and friends for sticking to your healthy eating plan and physical activity lifestyle* had the second

highest percentage of the time reported for the total sample, black, and successful participants, while it ranked third for white and fourth for unsuccessful participants. The strategy that was used for the third highest mean percentage of the time in the total sample and the successful participants was *modifying your recipes when making foods (reducing or substituting high-fat or high-calorie ingredients with healthier choices)*. This strategy was second for white participants, third for unsuccessful participants and fifth for black participants. Ranking in either the fourth or the fifth highest mean percentage of the time for all groups except the unsuccessful participants was *weighing yourself on a regular basis to prevent weight gain*. This strategy ranked sixth for the unsuccessful participants, and this group weighed themselves regularly less than 46% of the time. Also among the top five strategies for all groups was *increasing your daily physical activity (take the stairs, park further away, walk instead of drive)*.

Participants were asked if they had regained 2 or more pounds during the 18-month period, and 89 individuals answered “yes.” Those who responded affirmatively were asked to indicate what percentage of the time they used their restart plan to prevent further weight gain. The mean percentage of the time individuals used the restart plan was low for the total sample and all groups, ranging from 35.4% to 46.4% of the time (Table 5.2).

We checked for differences in behavioral strategy use between the black and white participants and the successful and unsuccessful participants. We found only one significant difference in strategy use between the racial groups, *modifying recipes when making foods*,  $t_{(105)} = 2.01$ ,  $p = .04$ . Black participants used this strategy less frequently ( $M = 45.0\%$ ,  $SD = 31.0\%$  of the time) than white participants ( $M = 56.8\%$ ,  $SD = 24.3\%$  of the time). However, no differences in strategy use were found between the successful and unsuccessful participants,  $ps > .17$ .

Additionally, we examined the use of behavioral strategies for weight maintenance for successful and unsuccessful participants within and between each racial group. Again, the most commonly used strategy for all groups was reading food labels. Mean percentages of the time groups used this strategy (with standard deviations in parentheses) were 66.8% (25.1%), 66.4% (31.0%), 67.7% (26.9%), and 55.0% (36.1%) for successful white, successful black, unsuccessful white, and unsuccessful black participants, respectively. When assessing for differences in strategy use between the successful white ( $n = 47$ ) and successful black ( $n = 14$ ) participants, we found no significant differences between these subgroups; the percentage of the time that the restart plan was used to prevent further weight gain was marginally significant,  $U = 132.5$ ,  $Z = -1.85$ ,  $p = .07$ , all other  $ps > .19$ . Successful white participants used their restart plan less ( $M = 35.0\%$ ,  $SD = 27.6\%$  of the time) than successful black participants ( $M = 53.6\%$ ,  $SD = 28.4\%$  of the time). A comparison of unsuccessful white ( $n = 34$ ) and unsuccessful black ( $n = 12$ ) participants revealed a significant difference between the two groups in the amount of time that portion control methods were used to control food intake,  $t_{(44)} = 2.22$ ,  $p = .03$  ( $M = 44.7\%$ ,  $SD = 28.2\%$  and  $M = 24.2\%$ ,  $SD = 25.7\%$  for unsuccessful white participants and unsuccessful black participants, respectively). No differences in strategy use were found within racial groups between successful white and unsuccessful white participants,  $ps > .35$ , or between successful black and unsuccessful black participants,  $ps > .14$ .

## 5.5 DISCUSSION

The purpose of this study was to examine the use of behavioral strategies for weight maintenance 18 months after the completion of a behavioral weight loss trial. We found that the most popular

behavioral strategy used in this follow-up period was reading food labels. This strategy had the highest mean usage for the total sample and all groups. Others have reported a significant association between label reading and decreased fat intake in population-based surveys (Guthrie & Saltos, 1995; Neuhouser, Kristal, & Patterson, 1999; Satia, Galanko, & Neuhouser, 2005). Another trial reported that 96% of the participants stated they paid more attention to the number of fat grams and amount of cholesterol in the items they bought because of label reading (Medeiros & Zies, 1996). The PREFER trial's weight loss intervention emphasized limiting fat intake as a means of reducing caloric intake, and PREFER II found that participants reported using food label reading as a means of increasing their awareness of the nutritional content of foods. An interesting follow-up question might have been, "After reading the label, did you elect not to purchase foods that were high in calories or fat grams?" since our question did not inquire about whether or not reading the label actually influenced their behavior. However, a majority of the participants were successful weight maintainers suggesting that the use of this strategy increased awareness of calorie and fat content and might have resulted in individuals not purchasing unhealthful items.

We found one significant difference in behavioral strategy use between the black and white participants in PREFER II; white individuals modified recipes to reduce or eliminate high-fat or high-calorie ingredients more often than black individuals. The intervention materials for the PREFER trial were based upon the established method of standard behavioral therapy for weight loss but were not tailored to the specific eating or food preparation preferences of any cultural group, keeping in mind that the influence of cultural factors on preferences may vary considerably among individual members of a racial group (Kumanyika & Morssink, 1997). Yet, changing certain food practices within racial or ethnic groups might be resisted as these practices



are sometimes perceived as components of valuable cultural traditions (Airhihenbuwa et al., 1996; Dacosta & Wilson, 1996), and substituting ingredients that have cultural ties with more healthful alternatives may not have appealed to some of the black participants in our study. We also found a significant difference in the mean percentage of the time that portion control methods were used between unsuccessful black and unsuccessful white participants. Although both unsuccessful groups used this strategy for less than half the time, black individuals reported using portion control significantly less often than white persons did. An explanation for this finding of a between-race difference is not known but could possibly be attributed to the pressure to overeat in social situations that some black women have reported (Gans et al., 2003) or the importance of the shared social experience associated with eating for some black persons (Airhihenbuwa et al., 1996; Kumanyika, 2002), which could lead to less attention being paid to portion control.

A somewhat surprising finding was that most strategies learned during the PREFER trial were not used a majority of the time. The number of strategies that were used for more than half the time among the groups ranged from 2 to 4 of the 16 strategies. Other researchers have noted that participants do not continue to use behavioral strategies after weight loss treatment with only two strategies— eating in appropriate locations (kitchen, dining room) and eating only one portion at a meal— used for more than half of the follow-up period (Stalonas, Perri, & Kerzner, 1984). Yet, the majority of the participants in our study were considered successful at weight maintenance despite having used most strategies for less than half the time. A high usage of behavioral strategies is associated with improved weight maintenance (Befort et al., 2007; Kitsantas, 2000; Leser et al., 2002; McGuire et al., 1998; Wing & Hill, 2001), which is contradictory to our results. A possible explanation for these findings is that the survey required

the participant to recall what percentage of the time over the previous 18 months that he/she used each strategy. The recollection of behaviors over an extended period of time could have introduced inaccurate reporting as empirical findings suggest that the human memory is not trustworthy and the process of recalling information has the potential to introduce imprecision and bias (Hufford & Shiffman, 2003). An alternative explanation is that participants were using other strategies for weight maintenance that were not inquired about in the survey.

We found that there were no differences in behavioral strategy use between the successful and unsuccessful weight maintainers. A recent nationwide survey also found that the five most commonly reported behavioral strategies for weight control— eating a smaller amount of food, more fruits and vegetables, smaller portion sizes, fewer high-fat foods, and no sugared beverages— did not differ between those who had lost weight and kept it off compared to those who were unsuccessful at weight loss and maintenance (Kruger, Blanck, & Gillespie, 2006). Regular self-weighing has received particular attention recently as being associated with successful maintenance (Butryn, Phelan, Hill, & Wing, 2007; Kruger et al., 2006; Wing et al., 2006). Although there was not a significant difference in the use of this strategy between the successful and unsuccessful participants in our study, successful individuals did report weighing themselves for a greater proportion of the time. Perhaps the difference between these two groups might have been that the unsuccessful persons did not take corrective actions after seeing a weight gain on the scale. The finding of no significant differences between successful and unsuccessful participants could also be because of the nature of self-report data where it is difficult to determine whether actual behaviors are different. Additionally, previous research has found that some individuals fail to correctly estimate their eating and activity behaviors

(Lichtman, Pisarska, Berman, Pestone, Dowling et al., 1992; Muhlheim, Allison, Heshka, & Heymsfield, 1998).

Several strengths and a few weaknesses of this study exist. PREFER II was a long-term assessment of weight maintenance after behavioral weight loss treatment that adds to the limited amount of literature reporting on longer-term weight maintenance, since many trials do not examine maintenance beyond a year after weight loss (Early et al., 2007; Fogelholm et al., 1999; Harvey-Berino, Pintauro, & Gold, 2002; LeCheminant et al., 2005). We also investigated the strategies used by black individuals for weight maintenance, a group that has not been well-studied in terms of weight management (Kumanyika, Gary et al., 2005). Furthermore, 90% of the participants who completed the weight loss trial returned for PREFER II, reducing the potential for bias from a differential return of only those who maintained their weight. The main limitation of this study is the collection of self-report data. Although this method is the only means of collecting information on strategies used for weight maintenance, self-report is subject to social desirability as well as inaccuracy because of the limitations associated with participant recall, as discussed earlier. Fifty percent of the black participants and 62% of the white participants had a mean annual household income of  $\geq$  \$50,000; the mean education level was also somewhat high at 15.4 years for Whites and 14.7 years for Blacks. Thus, these results might be considered generalizable to persons with a higher socioeconomic level. Moreover, because health disparities are associated with low socioeconomic status (Lantz et al., 1998; Sorlie, Backlund, & Keller, 1995), examining behaviors used for weight maintenance in a sample that had a more diverse representation of education and income levels would be valuable. Additionally, we were unable to identify what behavioral differences existed between the successful maintainers and those who

were unsuccessful. Further exploration is warranted to determine what facilitated the success of the maintainers and what might have been missing for the unsuccessful group.

In conclusion, we found that most of the weight-control strategies participants learned during the PREFER trial's weight loss intervention were not often used in the 18 months following the study. Additional investigations should explore why strategies are not used after treatment ends so that future interventions can be modified to encourage participants' continuation of these strategies beyond the intervention period. No differences between successful and unsuccessful participants and few differences between black and white participants existed. Yet, further study could be directed toward incorporating culturally-tailored strategies into weight management programs in order to support the weight-control efforts of black individuals. This could include specific instruction on how to prepare healthier ethnic meals (Gans et al., 2003) or providing cookbooks for ethnic-style foods, e.g., Heart-Healthy Home Cooking African American Style (Kumanyika, Shults et al., 2005; U.S. Department of Health and Human Services, 1997). Even though more than half of participants were considered successful weight maintainers, future research must focus on determining how individuals make behavioral choices about weight management in order to establish ways to promote healthful dietary and activity behaviors long-term.

**Table 5.1: Sociodemographic and Baseline Characteristics for PREFER II Sample**

	Total		White		Black		Difference	
	(N = 107)		(n = 81)		(n = 26)		between groups	
Variable	n (%)		n (%)		n (%)		$\chi^2$	p
Gender								
Female	92 (86.0)		67 (83.0)		25 (96.0)		0.05 <sup>c</sup>	.11
Male	15 (14.0)		14 (17.0)		1 (4.0)			
Marital Status <sup>a</sup>								
Married/living with partner	75 (70.8)		63 (79.0)		12 (46.0)		10.08	<.01
Not married/separated	31 (29.2)		17 (21.0)		14 (54.0)			
Employment <sup>b</sup>								
Full time	83 (79.1)		59 (74.7)		24 (92.4)			
Part time	10 (9.5)		9 (11.4)		1 (3.8)		3.13 <sup>c</sup>	.21
Other	12 (11.4)		11 (13.9)		1 (3.8)			
Income <sup>a</sup>								
≤ \$30,000/yr	16 (15.1)		12 (15.0)		4 (15.4)			
\$30-50,000/yr	27 (25.2)		18 (22.5)		9 (34.6)		1.74 <sup>c</sup>	.44
≥ \$50,000/yr	63 (58.9)		50 (62.5)		13 (50.0)			
	Mean	SD	Mean	SD	Mean	SD	U	p
Variable	Median		Median		Median		z	
Education (years)	15.3	2.6	15.4	2.5	14.7	2.7	856.5	.15
(Range: 12-23)	16.0		16.0		14.5		-1.45	
Age (years)	46.3	6.9	46.1	7.1	46.8	6.4	1006.0	.73
(Range: 20-55)	48.0		48.0		48.5		-0.34	

	<b>Total</b>		<b>White</b>		<b>Black</b>		<b>Difference</b>	
	<b>(N = 107)</b>		<b>(n = 81)</b>		<b>(n = 26)</b>		<b>between</b>	
							<b>groups</b>	
	<i>Mean</i>	<i>SD</i>	<i>Mean</i>	<i>SD</i>	<i>Mean</i>	<i>SD</i>	<i>t</i>	<i>p</i>
<b>Variable</b>	<i>Median</i>		<i>Median</i>		<i>Median</i>			
<b>Weight (lbs)</b>	193.9	33.3	191.7	33.5	200.7	32.4	-1.20	.23
(Range: 126.7-264.4)	192.9		192.0		199.1			

*Note.* *SD* = Standard deviation; *U* = Mann Whitney U; *t* = t-value *p* = p-value; *z* = z-value.

<sup>a</sup>One white participant had missing data. <sup>b</sup>Two white participants had missing data. <sup>c</sup>Fisher's exact test.

**Table 5.2: Percentage of the Time Each Behavioral Strategy was Used by the Total Sample and Each Group**

	Total		Black		White		Successful		Unsuccessful	
	(N = 107)		(n = 26)		(n = 81)		(n = 61)		(n = 46)	
Strategy- “How often did you...”	Mean	SD	Mean	SD	Mean	SD	Mean	SD	Mean	SD
1. Read food labels while grocery shopping looking at total calories, fat grams, and healthy claims (“reduced fat,” “low-cal”, “light”)?	65.7	27.7	61.2	33.3	67.2	25.7	66.7	26.3	64.3	29.6
2. Feel you had the support of family and friends for sticking to your healthy eating and physical activity plan?	54.6	33.2	53.8	33.7	54.8	33.2	55.9	33.9	52.8	32.4
3. Modify your recipes when making foods (reducing or substituting high-fat or high- calorie ingredients with healthier choices)?	53.9	26.4	45.0	31.0	56.8	24.3	54.5	27.4	53.0	25.3
4. Increase your daily physical activity (take the stairs, park further away, walk instead of drive)?	51.6	27.9	50.4	27.2	51.9	28.4	49.8	29.1	53.9	26.4

	<b>Total</b>		<b>Black</b>		<b>White</b>		<b>Successful</b>		<b>Unsuccessful</b>	
	<b>(N = 107)</b>		<b>(n = 26)</b>		<b>(n = 81)</b>		<b>(n = 61)</b>		<b>(n = 46)</b>	
<b>Strategy- “How often did you...”</b>	<i>Mean</i>	<i>SD</i>	<i>Mean</i>	<i>SD</i>	<i>Mean</i>	<i>SD</i>	<i>Mean</i>	<i>SD</i>	<i>Mean</i>	<i>SD</i>
<b>5.</b> Use weighing yourself on a regular basis to prevent weight gain?	48.6	32.4	46.2	36.6	49.4	31.2	50.7	33.3	45.9	31.4
<b>6.</b> Handle cues (triggers) in your surroundings that may promote unhealthy choices (popcorn at the movies, snacking while watching T.V., high calorie vending machines) and select a healthier choice?	46.0	26.0	42.3	27.3	47.2	25.6	46.4	26.0	45.4	26.3
<b>7.</b> Self-monitor your physical activity including type of activity and total minutes?	44.0	30.5	40.8	29.1	45.1	31.1	41.5	31.8	47.4	28.8
<b>8.</b> Use problem-solving tips in situations where it is difficult to follow a healthy eating plan (e.g., eating a healthy snack before a party, ordering from a light menu, packing a low-calorie lunch for work)?	43.4	27.2	40.0	29.5	44.4	26.5	42.9	27.1	43.9	27.7



	<b>Total</b>		<b>Black</b>		<b>White</b>		<b>Successful</b>		<b>Unsuccessful</b>	
	<b>(N = 107)</b>		<b>(n = 26)</b>		<b>(n = 81)</b>		<b>(n = 61)</b>		<b>(n = 46)</b>	
<b>Strategy- “How often did you...”</b>	<i>Mean</i>	<i>SD</i>	<i>Mean</i>	<i>SD</i>	<i>Mean</i>	<i>SD</i>	<i>Mean</i>	<i>SD</i>	<i>Mean</i>	<i>SD</i>
<b>9.</b> Include scheduled physical exercise in your day?	43.1	30.9	38.5	29.4	44.6	31.4	42.1	32.6	44.3	28.8
<b>10.</b> Change negative thoughts you were having (excuse-making, “all or nothing” thinking, pessimism) that could interfere with your healthy eating and physical activity plan?	41.3	27.4	43.1	31.7	40.7	26.0	39.3	27.2	43.9	27.6
<b>11.</b> Use increasing physical activity to prevent weight gain?	41.3	28.9	36.2	27.9	43.0	29.2	42.5	30.0	39.8	27.8
<b>12.</b> Use portion control methods (weighing your food, using references of serving size, etc.) to control your food intake?	39.2	28.0	32.3	26.1	41.4	28.4	39.0	27.7	39.3	28.8

	<b>Total</b>		<b>Black</b>		<b>White</b>		<b>Successful</b>		<b>Unsuccessful</b>	
	<b>(N = 107)</b>		<b>(n = 26)</b>		<b>(n = 81)</b>		<b>(n = 61)</b>		<b>(n = 46)</b>	
<b>Strategy- “How often did you...”</b>	<i>Mean</i>	<i>SD</i>	<i>Mean</i>	<i>SD</i>	<i>Mean</i>	<i>SD</i>	<i>Mean</i>	<i>SD</i>	<i>Mean</i>	<i>SD</i>
<b>13.</b> Practice being assertive with others to meet your healthy lifestyle goals (e.g. reminding others of your healthy eating plan and not giving in to pressure to eat)?	38.5	30.7	37.3	30.7	38.9	30.9	39.2	30.1	37.6	31.9
<b>14.</b> Self-monitor your food intake including total calories and total fat grams?	37.4	28.2	38.5	31.6	37.0	27.2	40.7	29.3	33.0	26.3
<b>15.</b> Use reminders in your surroundings for doing physical activity (keep tennis shoes in sight, set an alarm to remind you to be active, make an activity date with a friend)?	35.4	30.3	32.3	26.1	36.1	31.0	34.9	32.2	36.1	27.8
<i>Did you regain 2 or more pounds?</i>	Yes, n = 89		Yes, n = 22		Yes, n = 68		Yes, n = 49		Yes, n = 40	
• How often did you use your “restart plan” to prevent further weight gain?	38.1	27.9	46.4	29.8	35.4	37.0	39.2	28.6	36.7	27.5

## 6.0 RESULTS MANUSCRIPT #3

Dietary Intake and Physical Activity as Potential Mediators of the Relationship between Psychosocial Variables and Weight Maintenance

### 6.1 ABSTRACT

**Objective:** To explore the roles of calorie intake, fat gram intake, and physical activity as potential mediators of the relationship between weight maintenance and barriers to healthy eating, low-fat diet experiences, self-efficacy, social support and stress. **Methods:** PREFER II was an ancillary study to assess predictors and mediators of weight maintenance 18 months after the completion of a behavioral weight loss trial. We weighed participants in light clothing without shoes and used the following instruments to measure psychosocial variables: Barriers to Healthy Eating (BHE), Experiences Following a Low-Fat Diet (ELF), Weight Efficacy Lifestyle (WEL), and Self-Efficacy for Exercise. We measured social support with a composite variable of two subscales from the ELF and BHE and measured stress from four survey items. Dietary intake was assessed using two 24-dietary recalls, and physical activity was measured by the Paffenbarger Activity Questionnaire. We employed linear regression models to examine the relationship of psychosocial variables with percent weight change and the potential mediation effects of dietary intake and physical activity. **Results:** The sample ( $N = 116$ ) was mostly female

(85.0%) and middle-aged ( $M = 45.9$ ,  $SD = 7.5$  years). Dietary intake and physical activity did not mediate the relationship between psychosocial predictors and weight maintenance; however, the BHE, ELF, WEL and the effect of a stressful life event on eating were significant predictors of weight change,  $ps < .03$ . An increase in the BHE also predicted increased fat gram intake,  $p = .048$ . **Conclusions:** Dietary intake and physical activity were not mediators of weight change after a behavioral weight loss trial, but these results identify several target areas, e.g. decreasing barriers to healthy eating and augmenting stress-management skills, for future directions in weight maintenance interventions.

## 6.2 INTRODUCTION

With the national and global rates of obesity at an all-time high (Eckel et al., 2004; Ogden et al., 2006), research is needed to understand the mechanisms by which an increasing number of individuals are at an unhealthy weight. Because weight loss programs seem to be beneficial for helping individuals lose weight initially (Jeffery et al., 2000), of particular interest is the problematic aspect of weight regain after treatment. Evidence suggests that several factors are associated with successful weight maintenance after a loss, e.g., self-efficacy (DePue et al., 1995), social support (Perri, Sears, & Clark, 1993; Wolfe, 2004), and a capacity for coping with life stress (Elfhag & Rossner, 2005). Developing a dislike for the taste of fat has been documented among those adherent to a low-fat diet (Urban et al., 1992), which could promote weight maintenance in the long-term, while barriers to eating a healthy diet are an inhibiting factor (Andajani-Sutjahjo et al., 2004; Davis et al., 2005). Yet, little information is available regarding how these variables influence weight maintenance.

Certain process variables might be responsible for or mediate the effect of psychosocial factors on weight management. For example, reduced caloric intake and increased physical activity are necessary for weight loss, and empirical evidence shows that continuation of these behaviors long-term is beneficial for weight maintenance (Shick et al., 1998; Wing & Phelan, 2005). It is possible that psychosocial factors, e.g., self-efficacy, social support, may exert their influence on weight management through an effect on dietary intake and physical activity. Some studies have examined the role of mediators of weight loss (Linde et al., 2006; Perri et al., 2001; Pescatello & VanHeest, 2000; White, Martin, Newton, Walden, York-Crowe et al., 2004), but no investigations were found examining mediators of weight maintenance after a weight loss trial. Therefore, the purpose of this study was to explore dietary intake, i.e., calorie and fat gram intake, and physical activity as possible mediators of the relationships between weight maintenance after a behavioral weight loss trial and 1) barriers to healthy eating, 2) experiences associated with following a low-fat diet, 3) self-efficacy for resisting eating and for exercising, 4) social support, and 5) stress. In statistical mediation, a mediator variable affects the relationship between the independent and dependent variables of interest and is the means through which a predictor influences the outcome variable (Baron & Kenny, 1986). This phenomenon is depicted in Figure 6.1. For example, we explored if each psychosocial predictor affected weight maintenance (path a) and affected the mediator (path b). In path c, the mediator should significantly predict weight maintenance after controlling for the psychosocial predictor. A significant test of mediation would result if, after controlling for the influence of the mediator on weight maintenance, the effect of the psychosocial predictor on weight maintenance (path a) was eliminated (complete mediation) or reduced (partial mediation) (Baron & Kenny, 1986).

### 6.3 METHODS

This follow-up study, PREFER II, took place 18 months after the end of a randomized clinical trial of behavioral weight loss treatment, PREFER. For PREFER, persons were recruited from the community in three cohorts and were randomly assigned to receive their preferred dietary intervention or not receive their preference (Preference-Yes or Preference-No) as well as to one of two dietary plans— a reduced-calorie and reduced-fat standard diet or a reduced-calorie and reduced-fat lacto-ovo-vegetarian diet. Standard behavioral therapy for weight loss was used during the course of the one-and-a-half year trial with group intervention sessions decreasing in frequency over time. Further details concerning the design and findings of the PREFER trial have been published elsewhere (Burke, Choo et al., 2006; Burke et al., 2007; Burke, Styn et al., 2006; Burke, Warziski et al., 2008). At the completion of the trial, the mean weight loss was between 4% and 8% for the four groups with a similar observed weight loss for participants in the lacto-ovo-vegetarian diet groups compared to the standard diet groups. A larger weight loss was observed for persons randomly assigned to not receive their preference compared to persons who were randomized to receive their preferred dietary treatment (Burke, Warziski et al., 2008).

For PREFER II, we contacted participants to return for a follow-up investigation 18 months after the PREFER trial had ended. Individuals were not informed during their time in PREFER that any future study would take place, and we did not contact participants prior to requesting their participation in PREFER II. We measured participants' weights and several factors believed to be related to weight maintenance (barriers to healthy eating, experiences associated with following a low-fat diet, self-efficacy for resisting eating and for exercising, stress, social support, calorie and fat gram intake, and physical activity). The inclusion and exclusion criteria of PREFER established the eligibility criteria for PREFER II— 18-55 years

old, agreeable to random assignment to their treatment preference or not and one of the two diet interventions, body mass index (BMI) between 27 and 43 kg/m<sup>2</sup>, and submitted an adequately completed 5-day food diary. Individuals were excluded if they had a medical condition that required they follow a physician-managed diet or activity plan (e.g. diabetes, recent myocardial infarction), had physical problems that limited their ability to exercise, their alcohol intake exceeded four or more daily drinks, or their regular food intake did not include meat, fish or poultry. Persons were also excluded because of pregnancy or a planned pregnancy during PREFER, treatment for a psychological diagnosis, current use of weight loss pharmacotherapy or participation in a weight loss program within the past six months. The baseline measure for PREFER II was the PREFER final assessment; thus individuals were required to have completed PREFER in order to participate in PREFER II. One hundred nineteen, or 90%, of the individuals in 3 cohorts who finished PREFER participated in PREFER II between February 2006 and April 2007. Three of these 119 participants were excluded from PREFER II as two were pregnant and one indicated that she had a binge eating disorder, for a sample size of 116.

### **6.3.1 Weight**

The Tanita Digital Scale was used to measure weight in pounds with participants wearing light clothing and no shoes. For one out-of-town participant, we obtained a self-reported current weight. Self-reported weights have been noted as valid in previous studies (Kuczmarski et al., 2001; Spencer et al., 2002), and two kilograms were added to this self-reported value to correct for possible under-reporting. This corrective action has been reported by others (Kramer et al., 1986; Linde, Jeffery et al., 2004; Palta et al., 1982).

### 6.3.2 Psychosocial predictors

Psychosocial variables of interest included the Experiences Associated with Following a Low-fat Diet Scale (ELF), Barriers to Healthy Eating Scale (BHE), Weight Efficacy Lifestyle Questionnaire (WEL), Self-Efficacy for Exercise Scale (SEE), social support and stress. A composite score of three items from the BHE scale and four items from the ELF scale measured family and friend social support as determined by factor analysis (Burke et al., 2004; Kim et al., 2004). Four survey items assessed stress: “Have you had a major stressful event (such as marriage, new job, divorce, death in the family) in the last 18 months? If yes, please describe.” “On a scale of 0 (no effect) to 10 (most effect), how much did this stressful event affect your eating habits?” “On a scale of 0% to 100% of the time, how often does stress influence how you eat?” “On a scale of 0% to 100% of the time, how often do you use tricks to lower your stress level (deep breathing, journal writing, exercise, relaxing hobbies, time management, etc.)?” We developed the survey for PREFER II and pilot tested it in a group of individuals seeking weight loss treatment who found it easy to follow and complete. We administered the ELF, BHE and WEL in PREFER and PREFER II, but the SEE and the four survey items measuring stress were included in PREFER II only.

The ELF questionnaire measured experiences believed to be associated with the maintenance of a low-fat diet—wellness (feeling healthier when following the diet), distaste (for fat), cost (financial and time), inconvenience (following the diet when not eating in the home), deprivation (denied favorite foods), and family (inadequate family support). It has a 5-point scale (1 = strongly disagree to 5 = strongly agree) and was validated during the Women’s Health Trial ( $r = .26$  to  $.76$ ) (Urban et al., 1992). Higher scores denoted experiences that are more positive. Cronbach’s alpha for this study was satisfactory at .81 (Nunnally & Bernstein, 1994).



In the BHE questionnaire, participants rated on a scale of 1 (no problem) to 5 (very important problem) different situations associated with adhering to the healthy eating plan (emotions, daily mechanics of following the eating plan, social support), e.g., “It is difficult to motivate myself to eat appropriately” or “Changing my diet to reduce calories and fat seems too complicated.” Higher scores indicated more barriers. In the PREFER trial, Cronbach’s alpha was .86 (Burke et al., 2004), and  $\alpha = .89$  for PREFER II suggesting good internal consistency.

The WEL questionnaire assessed self-efficacy for weight management (Clark et al., 1991). This tool assessed the participant’s confidence in the ability to resist eating under varying circumstances on a scale of 0 to 9, e.g., “I can resist eating when I am at a party.” Higher scores indicated greater confidence. Psychometric properties are well-established (Clark et al., 1991), and Cronbach’s alpha for this study was high at .94. The validity and reliability of this measure was also established in African American women (Dutton et al., 2004).

Administered only at PREFER II, the SEE is a measure of self-efficacy for exercise (Resnick & Jenkins, 2000) in which individuals were asked to rate, on a scale of 0 (not confident) to 10 (very confident), their confidence in their ability to exercise 3 times per week for 20 minutes given a variety of conditions, e.g. you were busy with other activities or you felt tired. Higher scores indicated greater confidence in the ability to exercise. Good internal consistency ( $\alpha = .92$ ) has been reported (Resnick & Jenkins, 2000). Cronbach’s alpha coefficient for PREFER II was comparable at .93.

Three items from the BHE and four items from the ELF were combined as a measure of one’s perception of his/her social support from friends and family for following a healthy eating lifestyle. A lower score indicated less social support. Cronbach’s alpha was .78 indicating acceptable internal consistency for this measure of social support.

### **6.3.3 Potential mediators**

Two unannounced 24-hour dietary recalls, which have been shown to be reliable in adults and children (Conway, Ingwersen, & Moshfegh, 2004; Freund, Johnson, Silverstein, & Thomas, 1991), were conducted to collect dietary intake data in PREFER II. The trained interviewer used the Nutrition Data System for Research (NDSR) software, and comprehensively reviewed, for one workday and one non-working day, all foods and drinks the participant consumed in the previous 24 hours. The NDSR software, maintained by the Nutrition Coordinating Center at the University of Minnesota (The University of Minnesota Nutrition Data System for Research, [www.ncc.umn.edu](http://www.ncc.umn.edu), accessed 5 June 2008), contains over 18,000 foods, 8,000 brand name products, and a number of ethnic and regional food items. We instructed participants on how to complete the dietary recall and provided measurement references to help them judge their portion sizes. The dietary data from the PREFER study final assessment came from 3-Day Food Diaries where participants recorded everything that they ate or drank on 2 working days and one leisure day. A dietician reviewed these diaries with each participant for completeness and accuracy. The data from the diaries were also analyzed using this same nutrient software. We derived an average calorie and fat gram intake for the PREFER final assessment and for PREFER II.

In PREFER and PREFER II, we measured physical activity by self-report via the Paffenbarger Activity Questionnaire (PAQ) (Paffenbarger, Wing, & Hyde, 1978), which provides an estimation of kilocalorie (kcal) expenditure for the past week through the assessment of number of city blocks normally walked each day, number of flights of stairs climbed daily, and leisure-time activities, e.g., total minutes of sports or recreational activities. A total weekly score for energy expenditure in kcals is derived by assigning 8 kcal to each city block, 4 kcal to

each flight of stairs and 5 kcal/min, 7.5 kcal/min or 10 kcal/min to light, moderate, or vigorous leisure-time activities, respectively. The PAQ has shown good test-retest reliability ( $r = .34$  to  $.72$ ), and validity is reported as  $r = .29$  with Caltrac Physical Activity Monitors and  $r = .62$  with  $\text{VO}_2$  max (Ainsworth, Haskell, Leon, Jacobs, Montoye et al., 1993).

#### **6.3.4 Statistical analysis**

SPSS (version 15.0, SPSS Inc., Chicago, IL 2006) was used for the analysis, and an alpha level of .05 was set for all two-sided hypothesis testing. Descriptive statistics (means, standard deviations, medians) were used to describe the study sample. As appropriate, we used chi-square tests of independence, Fisher's exact tests and  $t$ -tests or Mann Whitney U tests to examine sociodemographic and baseline variables for differences between those who participated in PREFER II and those who did not. We used percent change scores for all variables (predictor, mediator, dependent), i.e., change from baseline to PREFER II standardized by percent change from baseline, except for the SEE and three continuous stress items because we collected these variables only at PREFER II. Path analysis was employed to assess the roles of dietary intake (calorie and fat gram intake) and physical activity as possible mediators of the relationship between weight maintenance (percent change in weight) and the predictor variables (barriers to healthy eating, low-fat diet experiences, self-efficacy for resisting eating and for exercising, social support, stress). In order to examine mediation, regression models analyzing both the direct effect of each of the predictors on weight maintenance and their indirect effects through dietary intake and physical activity were fitted. According to Baron and Kenny (1986), we established three regression equations for each predictor, as appropriate. We first regressed the dependent variable (weight maintenance) on the predictor. If this regression model was

significant, we regressed each possible mediator on the predictor in the second step. If a mediator was significantly predicted by the predictor variable, we regressed the dependent variable on both the predictor and the mediator simultaneously in the third step (Baron & Kenny, 1986). The estimation of effect sizes using standardized path coefficients was examined rather than the strict testing of hypothesized relationships. Assumptions underlying simple linear regression i.e., normality of the error terms, homoscedasticity of error variance, independence of observations, linearity of variables, no outliers, were supported once the following remedial strategies were applied and influential outliers were removed from various models.

Two remedial strategies were employed with the PAQ scores for physical activity prior to conducting the regression analyses with this variable. Two participants reported no physical activity at baseline and one of these same persons reported no activity at PREFER II, giving them improbable zero scores. These zero values were handled using score alteration where these values were replaced with a value that was one kcal less than the lowest reported kcal expenditure for the sample so that they remained the lowest ranked value (Tabachnick & Fidell, 2001). Four participants' percent change scores were extreme and beyond the sample distribution at PREFER II; thus, these scores were also handled with score alteration and replaced with one percent above the highest score near the sample distribution, making them the highest ranked scores. Despite the application of these remedial measures, all histograms of standardized residuals with percent physical activity change in the model revealed a highly positively skewed distribution. Therefore, a log base 10 transformation was applied to the physical activity variable; this transformation was adequate to support the statistical assumptions. A square root transformation was utilized for the percent calorie change and percent fat gram change variables as histograms of standardized residuals showed moderately positively skewed

distributions; these transformations were also adequate to support the underlying assumptions of the regression model. Prior to data transformation, a constant value was added to variables that contained zero or negative values.

Sensitivity analyses were performed with and without potential outlying values, and nine influential outliers were identified in various regression models— two in the BHE, two in the WEL, one in physical activity, three in social support, and one in weight change predicted by the use of stress reducing techniques. These individuals were therefore removed from models in which they overly influenced the results. The first outlier was a 47-year-old white woman who experienced a 126% increase in barriers to healthy eating; her baseline BHE score was in the bottom 20% of the sample, but increased to the highest quartile of the sample. She lost 2 lbs (0.96%) during the PREFER trial and gained 7.7 lbs or 3.82% of her weight at PREFER II. A 46-year-old black woman had a 123% increase in her barriers to healthy eating score; her baseline BHE score was the fifth lowest in the sample and increased to the 50<sup>th</sup> percentile. She gained weight (1.7 lbs or 0.65%) during PREFER and gained an additional 10.8 lbs (4.07%) at PREFER II. One 53-year-old white woman had a 262.0% increase in self-efficacy for resisting eating (WEL) with the lowest score at baseline and a score that remained within the lowest quartile at follow-up. She lost 7.7 lbs (2.9%) during PREFER and gained 16 lbs (6.25%) at follow-up. The other outlier in the WEL was a 52-year-old white woman who had a 175% increase in her WEL score; she had the second lowest score at baseline and her score remained in the bottom third of the sample at follow-up. She gained 10.0 lbs (4.7%) during PREFER and gained 19.1 lbs (7.8%) at PREFER II. A 55-year-old black woman was an influential outlier when examining whether the WEL predicted physical activity. This woman had a 98.2% increase in her WEL score (the fourth lowest score at baseline to slightly below the fiftieth percentile at follow-up) and her

physical activity increased by 1791.9%. She reported no physical activity at baseline and 2629.8 kcal of physical activity at follow-up. Her baseline score and percent change score were part of the scores that underwent score alteration as described earlier.

Three outliers were identified when examining social support as a predictor of weight change. One was a 53-year-old white woman with a 100% increase in social support and the lowest score of the sample at baseline that remained in the bottom 10% of the sample at follow-up. She lost 5.5 lbs (2.5%) during PREFER and regained 1.5 lbs (0.7%) at follow-up. A 54-year-old white woman had an increase in social support of 94.4% with a score in the bottom 10% at baseline that increased to the highest possible score at follow-up. During PREFER, she lost 15.8 lbs (7.6%) and regained 1.5 lbs (0.7%) at PREFER II. The third outlier in this model was a 44-year-old black woman with an 83.3% increase in social support; her score was the second lowest at baseline and stayed in the bottom quartile of the sample at follow-up. She had no change in weight at the completion of PREFER and gained 11.8 lbs (6.7%) at PREFER II.

The last influential outlier was identified in the model with weight change predicted by the item, “On a scale of 0% to 100% of the time, how often do you use tricks to lower your stress level (deep breathing, journal writing, exercise, relaxing hobbies, time management, etc.)?” This 47-year-old black woman reported using stress reduction techniques for 0% of the time. She lost 55.7 lbs (24.8%) during the course of PREFER and regained 45.5 lbs (27%) at PREFER II.

## **6.4 RESULTS**

Sociodemographic characteristics of the 116 participants are presented in Table 6.1, and baseline, PREFER II follow-up, and percent change variables are shown in Table 6.2. The

sample was an average of 45.9 years old ( $SD = 7.5$  years). Participants were mostly female (85.0%), married or living with a partner (69.0%) and well educated ( $M = 15.3$ ,  $SD = 2.5$  years of education). They reported consuming an average of approximately 1488 calories and 47 grams of fat per day and expending about 3000 kcal in physical activity a week at baseline. Calorie and fat gram intake increased to a mean of 1712 calories and 64 grams of fat daily while energy expenditure decreased to 2306 kcal a week at follow-up. Participants who returned for PREFER II did not significantly differ from individuals who did not return for PREFER II in sociodemographic variables (age, gender, race/ethnicity, education, income, marital status,  $ps > .12$ ) or baseline variables (weight, BHE, ELF, WEL, social support, calorie or fat gram intake or physical activity,  $ps > .08$ ).

Table 6.3 shows the results of univariate regression models for each psychosocial variable predicting percent weight change. Self-efficacy for exercise, social support, how often stress influences eating, and how often participants used stress reduction techniques were not significant predictors of weight maintenance; therefore, the exploration of mediation was not pursued with these variables. The BHE, ELF and WEL as well as how much a stressful life event affected eating, in the subsample of participants who reported a stressful event, were significant predictors of weight maintenance. An increase in barriers to healthy eating and an increase in the effect of a stressful event on eating were associated with weight regain whereas a decrease in positive experiences associated with following a low-fat diet and a decrease in self-efficacy for resisting eating were associated with weight regain. Thus, calorie and fat gram intake and physical activity were explored as possible mediators of the relationship between these variables and weight change.

The potential mediators of calorie intake, fat gram intake and physical activity were not significantly predicted by the ELF ( $ps > .40$ ), the WEL ( $ps > .11$ ), or the effect of a stressful life event on eating ( $ps > .06$ ). See Table 6.4. The BHE did not significantly predict calorie intake ( $p = .55$ ) or physical activity ( $p = .29$ ), but was a significant predictor of fat gram intake. An increase in barriers to healthy eating was associated with an increase in fat gram intake. BHE and fat gram intake were then regressed on percent weight change together. In this step, the potential mediator, fat gram intake, did not significantly predict percent weight change ( $p = .58$ ), and statistical mediation of the effect of BHE on weight maintenance was not supported. See Figure 6.2 for standardized regression coefficients.

## **6.5 DISCUSSION**

Our findings did not support the roles of dietary intake and physical activity as mediators of the relationships between psychosocial variables and weight maintenance 18 months after a behavioral weight loss trial. We did find that barriers to healthy eating, experiences associated with following a low-fat diet, self-efficacy for resisting eating, and the impact of a stressful life event on eating were associated with weight change. Additionally, an increase in barriers to healthy eating predicted increased fat gram consumption in this follow-up study. Others have reported barriers related to healthful dietary intake that could affect weight maintenance (Eikenberry & Smith, 2004; Vijan et al., 2005). One of the major reported barriers to healthy eating in a study of weight maintenance was a concern about the taste of more healthful foods (Andajani-Sutjahjo et al., 2004). Because foods high in fat are often thought of as having more taste (Astrup, Toubro, Raben, & Skov, 1997), difficulty limiting fat intake may be an important



barrier to weight maintenance, as successful weight-loss maintainers report continuing to follow a diet low in fat (Shick et al., 1998). Research has focused on continuing to eat a low-fat diet as a method of weight management (Astrup et al., 2000; Lindstrom et al., 2006; Shick et al., 1998; Swinburn et al., 2001); therefore, helping individuals keep in mind the positive aspects of this eating plan, e.g. cardiovascular risk reduction, feeling healthier, may be essential to promoting the continuation a diet lower in fat.

Unsuccessful weight maintenance is related to inadequate coping or problem-solving skills (Drapkin et al., 1995; Kayman et al., 1990), which might have been present in the subsample of individuals who reported experiencing a stressful life event. We did not inquire about specific strategies participants used to cope with the stressful life event, but the moderately high mean score of 7.1 out of 10 for the effect of the event on eating habits suggests that these individuals might use eating to cope with stress. Moreover, the physiologic effects of stress can increase appetite and food intake (Newman et al., 2007; Tataranni, Larson, Snitker, Young, Flatt et al., 1996), reinforcing the value of using a constructive manner of coping with stress. Future studies should explore problem solving and stress management techniques as a means of preventing weight regain.

The role of self-efficacy in weight loss has been extensively studied (Dennis & Goldberg, 1996; Linde, Jeffrey, Levy, Sherwood, Utter et al., 2004; Richman, Loughnan, Droulers, Steinbeck, & Caterson, 2001); however, less is known about the influence of self-efficacy on weight maintenance. While we found self-efficacy was associated with weight change, the effect was not mediated through dietary intake or physical activity. Linde and associates found that the effect of self-efficacy on weight loss during treatment was mediated by weight control behaviors, e.g., the number of days participants followed the dietary plan and their perceived effort for

following the weight loss protocol (2006). Yet, these authors found that self-efficacy was not as strong of a predictor of more specific measures of diet and physical activity like fat consumption or flights of stairs climbed, which is similar to our findings for weight maintenance.

Some limitations to our study should be noted. The socioeconomic level of our sample was fairly high with over 58% of participants reporting an annual household income of at least \$50,000, and the minimum level of education was 12 years with a sample mean of 15.3 years. These sample characteristics may limit the generalizability of our findings to individuals who are of a higher socioeconomic status. With the exception of weight, we assessed all study variables using self-report measures. Because no objective tools are currently available, the assessment of dietary intake is limited to self-report. Unfortunately, under-reporting of dietary intake has been noted (Hill & Davies, 2001; Martin, Su, Jones, Lockwood, Trichler et al., 1996), especially in the overweight or obese (Johansson, Wikman, Ahren, Hallmans, & Johnansson, 2001; Muhlheim et al., 1998). The accuracy of the dietary assessment could also be impacted by memory, estimation of portion size, or the description of food preparation techniques (St. Jeor, 2002). Additionally, dietary intake was measured using a 3-Day Food Diary in PREFER and two 24-hour dietary recalls in PREFER II. Although both of these measures were analyzed for calorie and fat gram intake using the NDSR software, there could have been some difference in self-reported food intake. The 3-Day Food Diary is a planned recording of foods consumed and might influence eating behavior while the 24-hour dietary recall is unannounced and collects data about past behavior. Physical activity was also measured using a self-report instrument, which is susceptible to bias, imprecision, and overestimation (Prentice, 2002). Moreover, over-reporting of physical activity has been noted in persons with a higher BMI (Irwin, Ainsworth, & Conway, 2001; Jakicic, Polley, & Wing, 1998; Walsh, Hunter, Sirikul, & Gower, 2004), which could have

affected the robustness of our physical activity assessment. An objective measure of physical activity, e.g., accelerometer (Troiano, 2005), would have increased the accuracy of our assessment. While self-report is truly the only way to assess the participants' perceived barriers, experiences or confidence, using only one measurement tool may limit the inferences that can be drawn about these variables. Future investigations would benefit from using more than one tool for the self-reported assessment of variables of interest. However, this improvement in measurement precision must be balanced against participant burden.

In sum, we did not find that dietary intake and physical activity mediated the effects of psychosocial variables on weight maintenance after a behavioral weight loss trial. Yet, the findings suggest several areas of focus for weight maintenance interventions, e.g., decreasing barriers to healthy eating, increasing positive experiences with following a low-fat diet, increasing eating-related self-efficacy, and teaching individuals how to appropriately deal with stressful life events. Further research is needed to systematically identify the mechanisms or processes by which factors related to weight maintenance influence individuals' abilities to maintain their weight.

**Table 6.1: Sociodemographic Characteristics (N=116)**

Characteristic	<i>n (%)</i>	
<b>Gender</b>		
Female	99 (85.0)	
Male	17 (15.0)	
<b>Marital Status<sup>a</sup></b>		
Married/living with partner	79 (69.0)	
Unmarried/separated	36 (31.0)	
<b>Employment<sup>b</sup></b>		
Full time	90 (78.9)	
Part time	11 (9.6)	
Other	13 (11.4)	
<b>Income<sup>a</sup></b>		
≤ \$30,000/yr	18 (15.7)	
\$30-50,000/yr	30 (26.1)	
≥ \$50,000/yr	67 (58.2)	
	<i>Mean</i>	<i>SD</i>
<b>Characteristic</b>	<i>Median</i>	
<b>Education</b> (years)	15.3	2.5
(Range: 12-23)	16.0	
<b>Age</b> (years)	45.9	7.5
(Range: 20-55)	48.0	

*Note.* SD= Standard deviation; <sup>a</sup>One participant had missing data. <sup>b</sup>Two participants had missing data. <sup>c</sup>Three participants had missing data.

**Table 6.2: Baseline, PREFER II Follow-up and % Change Variables (N=116)**

	Baseline		PREFER II		% Change	
	<i>Mean</i>	<i>SD</i>	<i>Mean</i>	<i>SD</i>	<i>Mean</i>	<i>SD</i>
<b>Variable</b>	<i>Median</i>		<i>Median</i>		<i>Median</i>	
<b>Weight (lbs)</b>	192.5	33.2	200.6	3.8	4.46	5.8
(Range: 126.7-283.9)	191.8		197.7		4.3	
<b>BHE<sup>b</sup></b>	51.5	15.3	55.7	14.9	12.9	29.8
(Range: 22-110)	53.0		58.5		9.1	
<b>ELF<sup>c</sup></b>	88.3	2.6	88.1	11.5	0.9	11.8
(Range: 26-130)	87.0		87.0		0.0	
<b>WEL<sup>b</sup></b>	120.4	35.1	113.1	33.9	1.6	41.4
(Range: 0-180)	114.0		112.5		-4.3	
<b>Social support<sup>c</sup></b>	26.5	6.2	26.9	5.7	4.6	23.8
(Range: 7-35)	28.0		28.0		0.0	
<b>Calorie intake<sup>d</sup></b>	1488.4	383.0	1712.1	1647.1	19.1	34.9
(Range: 630.8-3038.1)	1473.5		478.8		14.6	
<b>Fat gram intake<sup>d</sup></b>	47.0	19.1	63.5	27.0	51.2	71.2
(Range: 13.1-154.1)	44.4		57.9		41.7	
<b>Physical activity<sup>b</sup></b>	2997.0	2506.2	2306.5	1698.5	53.9	293.1
(Range: 0-13,979.5)	2526.0		1860.5		-22.5	
<b>SEE</b>		N/A	5.4	2.5		N/A
(Range: 0-10)			5.7			
<b>Stress and eating<sup>e</sup></b>		N/A	56.4	30.0		N/A
(Range: 0-100%)			60.0			
<b>Stress reduction<sup>f</sup></b>		N/A	39.0	28.6		N/A
(Range: 0-100%)			40.0			

	<i>Mean</i>	<i>SD</i>	<i>Mean</i>	<i>SD</i>	<i>Mean</i>	<i>SD</i>
<b>Variable</b>	<i>Median</i>		<i>Median</i>		<i>Median</i>	
<b>Stressful event<sup>g</sup></b>	N/A		7.1	3.0	N/A	
(Range: 0-10)			8.0			

*Note.* BHE= Barriers to Healthy Eating Scale; ELF= Experiences Associated with Following a Low-Fat Diet Scale; SD= Standard deviation; SEE = Self-Efficacy for Exercise; WEL= Weight Efficacy Lifestyle Scale; SEE and stress were only assessed at PREFER II; thus, percent change scores are not applicable. <sup>a</sup>One participant had missing data. <sup>b</sup>Two participants had missing data. <sup>c</sup>Three participants had missing data. <sup>d</sup>Five participants had missing data. <sup>e</sup>How often does stress influence how you eat? <sup>f</sup>How often do you use tricks to lower your stress level (deep breathing, journal writing, exercise, relaxing hobbies, time management, etc.)? <sup>g</sup>How much did this stressful event affect your eating habits (for the subsample of 73 who reported experiencing a stressful life event)?

**Table 6.3: Univariate Models for Each Psychosocial Predictor Regressed on % Weight Change**

Predictor variable	<i>b</i>	<i>SE (b)</i>	<i>Standardized Beta</i>	<i>t-value</i>	<i>p-value</i>
BHE ( <i>N</i> =112)	0.09	0.02	.38	4.37	<.001
ELF ( <i>N</i> =113)	-0.12	0.04	-.24	-2.62	.01
WEL ( <i>N</i> =112)	-0.04	0.01	-.21	-2.27	.03
SEE ( <i>N</i> =116)	<0.01	0.02	<0.01	0.02	.98
Social Support ( <i>N</i> =110)	-0.02	0.03	-.07	-0.70	.49
Stress and eating <sup>a</sup> ( <i>N</i> =115)	0.02	0.02	.12	1.23	.22
Stress reduction <sup>b</sup> ( <i>N</i> =114)	-0.03	0.02	-.18	-1.93	.06
Stressful event <sup>c</sup> ( <i>n</i> =73)	0.47	0.22	.25	2.14	.03

*Note.* *Ns* vary due to missing data and deletion of influential outliers except for stressful event.

BHE= Barriers to Healthy Eating Scale; ELF= Experiences Associated with Following a Low-Fat Diet Scale; SE= Standard error; SEE= Self-Efficacy for Exercise Scale; WEL= Weight Efficacy Lifestyle Scale. <sup>a</sup>How often does stress influence how you eat? <sup>b</sup>How often do you use tricks to lower your stress level (deep breathing, journal writing, exercise, relaxing hobbies, time management, etc.)? <sup>c</sup>How much did this stressful event affect your eating habits (for the subsample of 73 who reported experiencing a stressful life event)?

**Table 6.4: Psychosocial Predictors Regressed on Potential Mediators**

<b>Psychosocial variables</b>	<b><i>b</i></b>	<b><i>SE (b)</i></b>	<b><i>Standardized</i></b>	<b><i>t-value</i></b>	<b><i>p-value</i></b>
<b>predicting calorie intake</b>			<b><i>Beta</i></b>		
BHE ( <i>N</i> =109)	<0.01	<0.01	.06	.61	.54
ELF ( <i>N</i> =109)	.01	.01	.08	.44	.40
WEL ( <i>N</i> =109)	<0.01	<0.01	<0.01	-.06	.95
Stressful event <sup>a</sup> ( <i>n</i> =69)	-.05	.06	-.10	-.84	.40
<hr/>					
<b>Psychosocial variables</b>	<b><i>b</i></b>	<b><i>SE (b)</i></b>	<b><i>Standardized</i></b>	<b><i>t-value</i></b>	<b><i>p-value</i></b>
<b>predicting fat gram intake</b>			<b><i>Beta</i></b>		
BHE ( <i>N</i> =109)	.02	.01	.19	2.00	.04
ELF ( <i>N</i> =109)	.01	.02	.04	.43	.67
WEL ( <i>N</i> =109)	<0.01	<0.01	-.02	-.24	.81
Stressful event <sup>a</sup> ( <i>n</i> =69)	-.09	.12	-.09	-.79	.43
<hr/>					
<b>Psychosocial variables</b>	<b><i>b</i></b>	<b><i>SE (b)</i></b>	<b><i>Standardized</i></b>	<b><i>t-value</i></b>	<b><i>p-value</i></b>
<b>predicting physical activity</b>			<b><i>Beta</i></b>		
BHE ( <i>N</i> =111)	<0.01	<0.01	-.10	-1.07	.29
ELF ( <i>N</i> =112)	<0.01	<0.01	<0.01	.03	.98
WEL ( <i>N</i> =111)	<0.01	<0.01	.15	1.62	.11
Stressful event <sup>a</sup> ( <i>n</i> =72)	-.03	.02	-.23	-1.94	.06

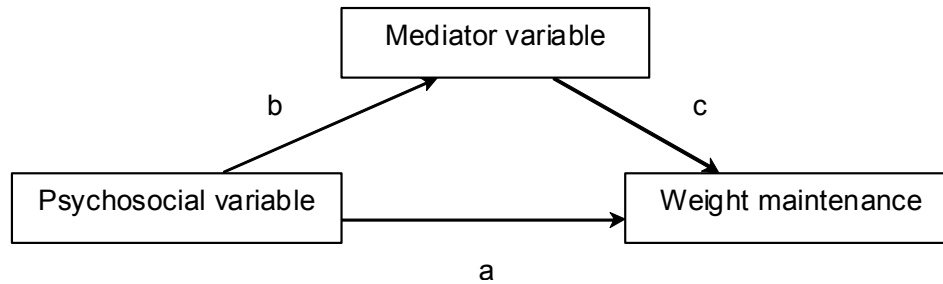
*Note.* *Ns* vary due to missing data and deletion of influential outliers. Calorie and fat gram

intake transformed using a square root transformation. Physical activity transformed using

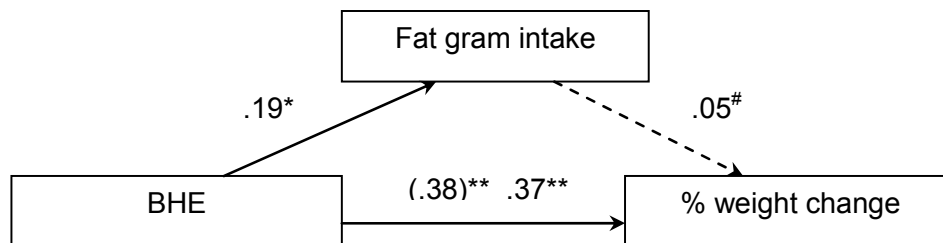
log base 10. BHE= Barriers to Healthy Eating Scale; ELF= Experiences Associated with Following a Low-Fat Diet Scale; SE= Standard error; WEL= Weight Efficacy Lifestyle Scale.

<sup>a</sup>How much did this stressful event affect your eating habits (for the subsample of 73 who reported experiencing a stressful life event)?





**Figure 6.1: Illustration of statistical mediation examined in PREFER II**



**Figure 6.2: Model of relationships among Barriers to Healthy Eating (BHE), fat gram intake, and % weight change.**

Values shown are standardized regression coefficients. The value in parentheses reflects the coefficient for the direct effect without fat gram intake in the model.  $*p < .05$ ;  $**p < .001$ ;  $^{\#}p = .58$ .

## **APPENDIX A**

### **PUBLISHED PRELIMINARY STUDY**

Changes in Self-Efficacy and Dietary Adherence: The Impact on Weight Loss in the PREFER Study

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# Changes in self-efficacy and dietary adherence: the impact on weight loss in the PREFER study

Melanie T. Warziski · Susan M. Sereika ·  
Mindi A. Styn · Edvin Music · Lora E. Burke

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**Abstract** Findings from studies examining self-efficacy and its relationship to weight loss have been inconsistent. We examined self-efficacy specific to changing eating behaviors in the PREFER trial, an 18-month behavioral weight-loss study, to determine if self-efficacy and dietary adherence were associated with weight change, and what impact self-efficacy had on weight change after controlling for adherence. Measurements included the weight efficacy lifestyle (WEL) questionnaire, body weight, self-reported fat gram intake, kilocalorie intake, and adherence to kilocalorie and fat gram goals at baseline, 6, 12, and 18 months. The sample ( $N = 170$ ) was 88.2% female and 70.0% Caucasian; the mean age was 44.1 years ( $SD = 8.8$ ). Mean weight loss at 18 months was 4.64% ( $SD = 6.24$ ) of baseline body weight and the mean increase in self-efficacy was 11.70% ( $SD = 38.61$ ). Self-efficacy improved significantly over time ( $p = 0.04$ ) and was associated with weight loss ( $p = 0.02$ ). Adherence to the fat gram goal was associated with weight loss ( $p = 0.0003$ ), and self-efficacy remained associated with weight loss after controlling for fat gram adherence ( $p = 0.0001$ ). Consistent with self-efficacy theory, improvement in self-efficacy over time

supported greater weight loss. Adherence to the fat gram goal also influenced weight loss.

**Keywords** Weight loss · Self-efficacy · Adherence · Vegetarian diet · Obesity

## Introduction

Obesity is a pervasive, chronic public health problem associated with multiple co-morbid conditions (Klein et al. 2004; Mokdad et al. 2003). Recommendations for overweight and obese individuals include losing and maintaining a loss of 5–10% of initial body weight in order to reduce the risk of developing chronic disorders such as coronary heart disease, hypertension, hyperlipidemia, and type 2 diabetes (Klein et al. 2004; Jakicic et al. 2001). Despite initial successes in weight-loss programs, the prevention of weight regain has remained a challenge (Jeffery et al. 2000). Typically, approximately a third of the weight an individual loses is regained within the first year after treatment (Wadden and Phelan 2002) and, at times, weight gain continues beyond the person's original pre-treatment weight. Assisting individuals in their efforts to continue behaviors that promoted the initial weight loss is a crucial concern for the health care community.

Weight-loss therapy can include the use of a limited number of available medications, surgical interventions for morbid obesity, and most commonly cognitive behavioral therapy. Also known as standard behavioral therapy, this treatment approach incorporates instruction and counseling in modifying behaviors, changing dietary intake to reduce the number of calories and amount of fat consumed, and increasing physical activity (Wing 1998). Adherence to the weight-loss treatment protocol, such as consuming the

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M. T. Warziski (✉) · S. M. Sereika · M. A. Styn ·  
E. Music · L. E. Burke  
Health & Community Systems Department, University of  
Pittsburgh School of Nursing, 415 Victoria Building, Pittsburgh,  
PA 15261, USA  
e-mail: mtw8@pitt.edu

S. M. Sereika  
Graduate School of Public Health, Department of Biostatistics,  
University of Pittsburgh, Pittsburgh, USA

S. M. Sereika · L. E. Burke  
Graduate School of Public Health, Department of Epidemiology,  
University of Pittsburgh, Pittsburgh, USA

prescribed amount of calories and fat grams, becomes a critical component of success. In fact, continued adherence to the prescribed diet has been found to be essential to weight loss success, regardless of the type of diet (Dansinger et al. 2005). A recent study examining the effects of a diet moderate in fat intake (30% of kilocalorie intake) compared to a diet low in fat (20% of kilocalorie intake) found that participants in the moderate-fat intake group experienced greater weight losses in the long term compared to those in the low-fat group; the authors suggested that dietary adherence in the moderate-fat intake group may have been easier to achieve and therefore resulted in more successful weight loss outcomes (Azadbakht et al. 2007). It has been proposed that allowing participants to choose their own treatment may improve adherence. Although therapeutic approaches for treating obesity have been studied for decades, providing an individual with his/her preference for weight-loss treatment is an area that has not been well researched, and results of examinations of preference for obesity treatment are mixed (Mendonca and Brehm 1983; Murray 1976; Renjilian et al. 2001). The existing literature does not include reports of the effects of both dietary adherence and self-efficacy on weight loss in the context of a clinical trial that included random assignment to receive one's preferred dietary treatment or not.

Self-efficacy, a component of social cognitive theory, is defined as an individual's judgment regarding his/her abilities to perform certain behaviors (Bandura 1997). The premise of self-efficacy is that beliefs regarding personal accomplishment or mastery (self-efficacy or efficacy expectancy) and desired outcomes (outcome expectancy) determine if persons will begin a behavior, what they will try to attain, and the degree of effort they will exert in a particular behavior (Bandura 1977). Self-efficacy describes the critical role a person's estimation of his/her capabilities plays in behavior change, and perceived self-efficacy, which is specific to certain activities, is a major determinant of performance independent of actual underlying skill (Bandura 1986). The strength of perceived self-efficacy is particularly important; individuals are more likely to continue their efforts until success is achieved if their perceived self-efficacy is higher (Bandura 1982). Four sources of self-efficacy include enactive attainment (actual performance of the task), vicarious experience (witnessing comparable people perform the task), verbal persuasion (informing a person that he/she has the ability to perform the task), and physiological feedback (physical cues to assess one's progress, e.g., less shortness of breath with stair-climbing) (Bandura 1997).

Empirical evidence is inconsistent in relating self-efficacy to weight loss. Investigators have found that higher weight-loss specific self-efficacy tends to predict more

successful weight loss and maintenance (Richman et al. 2001), and increased self-efficacy has been shown to be related to behaviors associated with weight loss, e.g. increasing dietary fiber (Hagler et al. 2007; Schwarzer and Renner 2000) decreasing fat intake (Nelson et al. 2007; Schwarzer and Renner 2000; Steptoe et al. 2000), and increasing fruit and vegetable consumption (Hagler et al. 2007; Henry et al. 2006; Van Duyn et al. 2001). In particular, Linde and colleagues found that greater eating self-efficacy prospectively predicted weight-loss behaviors such as higher total days in which participants were adherent to the dietary plan, counted their caloric intake, and consumed less fat. Yet, while self-efficacy predicted weight loss during the active intervention, it was not associated with weight change during the follow-up period (Linde et al. 2006). A study of 54 obese women found that those with the highest self-efficacy beliefs and greater self-esteem at baseline lost significantly more weight at the end of the intervention than the "disbelievers." Disbelievers were those who had less confidence in their ability to manage weight and gave up more readily (Dennis and Goldberg 1996). Conversely, researchers examining 106 overweight or obese African-American women found that higher levels of self-efficacy prior to treatment were associated with less weight loss, suggesting that high initial self-efficacy might actually indicate overconfidence or inexperience with the complexities of losing weight (Martin et al. 2003). Additionally, some have found that higher self-efficacy was not related to greater weight loss among adolescents (White et al. 2004), not significantly predictive of weight loss in men (Linde et al. 2004), and not associated with treatment program completion or weight loss (Fontaine and Cheskin 1997; Martin et al. 2002). Among 2,311 participants in a Web-based weight-loss program, individuals with higher self-efficacy at baseline were less likely to attend the follow-up assessment at 12 months (Glasgow et al. 2007).

The findings regarding self-efficacy and weight loss have been conflicting; furthermore, no weight-loss studies examining self-efficacy have incorporated the effect of adherence to the dietary protocol. Therefore, the purpose of this study was to examine if (1) increases in weight-loss specific self-efficacy were associated with weight loss over time, (2) higher adherence to the dietary protocol was related to weight loss, and (3) after controlling for dietary adherence, increases in self-efficacy were associated with weight loss, among participants in an 18-month, behavioral treatment weight-loss trial. A key component of the study's cognitive behavioral therapy involved educating participants about techniques to reduce fat and kilocalorie intake along with prescribing daily kilocalorie and fat gram goals based upon initial weight; therefore, we examined the effect of changes in kilocalorie intake and fat gram intake together with changes in self-efficacy as potential correlates

of weight loss. Also, because the self-efficacy instrument that was used specifically measured confidence in the ability to resist eating, we considered it important to examine changes in eating behaviors (i.e., changes in the intake of fat grams and kilocalories) and their relativity to weight loss and self-efficacy. Dietary adherence was based upon the amount of self-reported kilocalories and fat grams consumed in proportion to the prescribed daily goal.

## Methods

### Design and setting

This secondary analysis examined the temporal interrelationships among weight loss, self-efficacy, and dietary adherence data from the parent study, the PREFER trial, an 18-month behavioral weight-loss treatment study that randomized participants to receive their dietary treatment preference or not as well as to one of two treatment groups: standard behavioral treatment plus a standard calorie- and fat-restricted diet (STD-D) or standard behavioral treatment plus a calorie- and fat-restricted lacto-ovo-vegetarian diet (LOV-D). A detailed description of the design and randomization scheme for the PREFER trial can be found elsewhere (Burke et al. 2006). In brief, 932 adults were screened from September 2002 to May 2004. Two hundred participants were enrolled in three cohorts, stratified on race and gender, and then randomly assigned using minimization procedures (Pocock and Simon 1975) with a computer-generated program to treatment Preference-Yes or treatment Preference-No. The project data manager and statistician devised and oversaw the two-stage randomization process. Figure 1 displays a participant flow diagram from eligibility screening to completion of the study at 18 months. Those randomized to treatment Preference-Yes were assigned to their preferred diet plan (STD-D or LOV-D). Those randomized to treatment Preference-No were then randomized again to receive either STD-D or LOV-D, without regard to their dietary preference. Written, informed consent was obtained from all participants after approval by the University of Pittsburgh Institutional Review Board.

### Sample

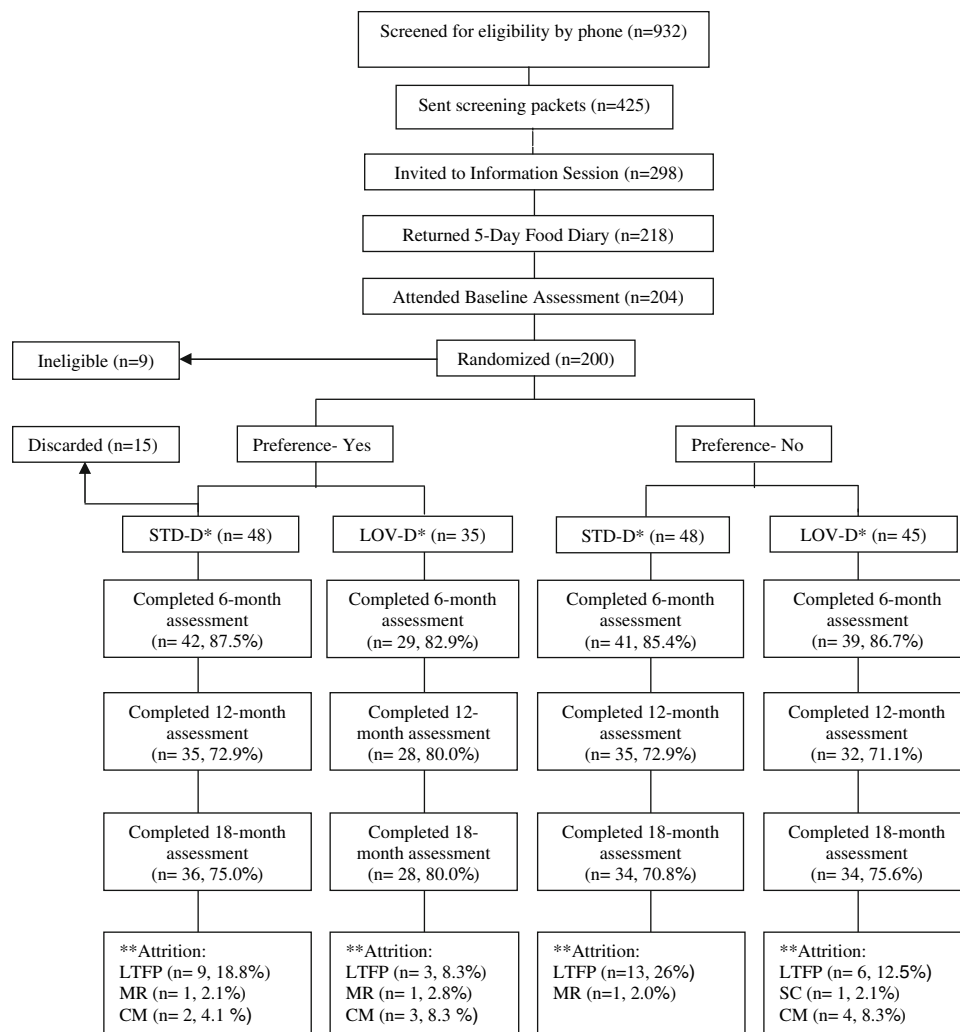
Participants were recruited from a large urban area in southwestern Pennsylvania. Eligibility criteria required that participants were 18–55 years old, agreeable to randomization to their treatment preference or not as well as to one of the two diet plans, had a body mass index (BMI) (i.e., weight in kilograms divided by height in meters squared) between 27 and 43, inclusively, and had adequately completed

a 5-day food intake diary to demonstrate that they could self-monitor their food intake. The age range was chosen to ensure an adult population that was young enough to have a limited occurrence of co-morbidities, such as osteoarthritis, that might prohibit participation in physical activity. Individuals were excluded if they had a serious illness requiring medical supervision, physical restriction preventing them from exercising, were pregnant or planning a pregnancy in the next 18 months, diagnosed with a psychological illness, drank  $\geq 4$  alcoholic beverages per day, had participated in a weight-loss program in the previous 6 months, were taking weight-loss or anti-depressant medications, reported a binge eating disorder, or were currently following a vegetarian diet.

### Intervention

Each treatment group received the same standard behavioral therapy and followed a calorie-restricted (1,200 kcal for women weighing  $< 200$  lbs, 1,500 kcal for women weighing  $\geq 200$  lbs, 1,500 kcal for men weighing  $< 200$  lbs, and 1,800 kcal for men weighing  $\geq 200$  lbs) and fat-restricted (25% of daily calories) diet for 18 months. The LOV-D group gradually eliminated all meat, fish, and poultry over the first 6 weeks of the study but was permitted to continue to eat dairy products, eggs, and meat flavorings. The standard behavioral treatment components of the intervention incorporated the four sources for increasing one's self-efficacy. Participants achieved enactive attainment when they lost weight and had vicarious experiences observing other group members lose weight. Interventionists and study staff provided verbal persuasion that the participant had the ability to lose weight, and participants received physiologic feedback after losing weight, for example, feeling more comfortable and experiencing less fatigue. Intervention sessions were approximately 1 h long and focused on teaching cognitive behavioral strategies for weight loss (e.g. self-monitoring food intake and physical activity, goal setting, feedback on progress and goal achievement with suggestions on how to improve, reinforcement of progress, problem solving, recipe modification, etc.). For the first 6 months, intervention sessions were held weekly, then biweekly for months 7 through 9, and monthly for months 10 through 12. A 6-month maintenance period followed and participants had no contact with the staff of the study except to arrange the 18-month assessment appointment. Body weight was measured and participant-maintained food-intake and physical activity records were submitted at each intervention session. The interventionists reviewed the diet and physical activity diaries and provided written feedback. Individuals were able to track their weight-loss progress in provided graphs, and feedback was given on physical and biological changes

**Fig. 1** Participant flow diagram



\* **STD-D** – Standard Diet; **LOV-D** – Lacto-Ovo-Vegetarian Diet

\*\***LTFP** – Lost to follow up; **MR** – medical reasons; **CM** – changed mind; **SC** – schedule conflict

after the 6-, 12- and 18-month assessments. All participants were instructed to increase their physical activity gradually over the first 6 weeks, primarily through walking, with a weekly goal of 150 min of activity. Burke et al. (2006) provided a complete description of the features of the standard behavioral treatment and intervention components elsewhere.

## Measures

The Weight Efficacy Lifestyle (WEL) Scale was used as the measure of self-efficacy specific to eating behaviors. Initially based on the smoking confidence questionnaire by Conditte and Lichtenstein (1981), the 20-item questionnaire asked participants to rate their confidence in their ability to avoid eating on a 10-point Likert scale, 0 (not confident) to 9 (very confident) (Clark et al. 1991). The WEL contains five components—negative emotions (‘I can resist eating when I am angry’), availability (‘I can control

my eating on the weekends’), social pressure (‘I can resist eating even when I have to say no to others’), physical discomfort (‘I can resist eating when I feel physically run down’), and positive activities (‘I can resist eating when I am watching TV’). Cronbach alpha coefficients ranged from 0.70 to 0.90 (Clark et al. 1991). The external validity of the WEL was also well established in six multidisciplinary weight-loss studies (Cargill et al. 1999; Clark et al. 1996; King et al. 1996; Miller et al. 1999; Pinto et al. 1999a, b). Scores range from 0 to 180 with higher scores indicating greater levels of self-efficacy. The WEL score for each participant was derived by totaling the numerical scores from each item; the WEL subscale scores were derived by totaling the scores from the four items that comprised each subscale.

Adherence to the dietary protocol, i.e., the kilocalorie goal and fat gram goal, was determined from the Three-Day Food Record used to evaluate food intake for nutrient analysis at each 6-month assessment point. The self-reported nutrient

intake was analyzed at the Obesity/Nutrition Research Center at the University of Pittsburgh using the Nutrition Data System-Research (NDS-R) (Buzzard et al. 1995). NDS-R analyses provided a mean kilocalorie and fat gram intake for each time point. The staff entering the data was blinded to the randomization group and assessment time point. Percent adherence to the fat gram and kilocalorie goal was determined by comparing the actual intake of fat grams and kilocalories to the individually prescribed amounts for each. Adherence was calculated as the amount consumed divided by the amount prescribed multiplied by 100. For example, if a participant consumed 1,100 kcal and the daily prescription was 1,200 kcal the person would be considered 91.7% adherent. Adherence was then categorized based upon three ranges; 0–84.99% (under consumers), 85.0–114.99% (adherers), and greater than or equal to 115% (over consumers).

Baseline, 6-, 12-, and 18-month weights and self-efficacy scores were examined as outcome measures for this analysis. Weight in kilograms was measured following an overnight fast using the Tanita scale and body fat analyzer with subjects wearing light clothing and standing bare foot on the scale's footpads. Multiple psychosocial instruments were administered at each assessment. For this report, only the WEL, a measure of self-efficacy for weight loss, was examined in relation to weight change. The primary outcome measures for this analysis included percent weight change and percent change in self-efficacy over time relative to baseline values.

### Statistical analysis

SPSS (Version 13, SPSS, Inc., Chicago, IL) and the SAS System for Windows (Version 9.1, SAS Institute Inc., Cary, NC) were used to analyze the data. The significance level for two-sided hypothesis testing was set at 0.05. Baseline values of descriptors and outcomes were examined for differences among the four treatment groups using chi-square and Fisher's exact tests for categorical variables and the *F*-test from an analysis of variance or a Kruskal-Wallis test for continuous variables. Missing values for longitudinal data were imputed using a combination of the last-observation-carried-forward (LOCF) and baseline value approaches. The LOCF approach for handling missing data is commonly used in clinical trials (Unnebrink and Windeler 2001) and has also been used by weight-loss researchers (Wadden et al. 2005; Toobert et al. 2005; Yeh et al. 2003; McManus et al. 2001). For 21 participants, baseline values were the last observations used for LOCF imputations because these persons were not assessed at any subsequent time points.

Linear mixed modeling via SAS PROC MIXED was used to examine correlates of weight change over time (1)

changes in self-efficacy and dietary intake (kilocalories and fat grams) over time and (2) changes in self-efficacy controlling for dietary adherence (kilocalorie and fat gram adherence) over time. Change was formulated as "percent change from baseline," computed as the change from a follow-up time point to baseline standardized by the baseline value and expressed as a percentage. The "heterogeneous Toeplitz" and the "unstructured" variance-covariance structures demonstrated the best fit to the repeated measures based on information criteria in the main self-efficacy models and the adherence models, respectively. Although not of primary interest in this secondary analysis, the design variables, i.e., the randomized assignment to preference (Yes, No) and diet (STD-D, LOV-D), along with time (6, 12, 18 months), were included in all models. Initially, a mixed model was estimated with self-efficacy change as the dependent variable, including the design variables and two-way interactions as independent variables, to determine if there was a difference in changes in self-efficacy over time among the randomized groups. For the dependent variable of weight change, mixed models were built hierarchically by first examining the main effects of the design variables, their two-way interactions and the three way interaction of diet  $\times$  preference  $\times$  time, which was not significant. Self-efficacy change was then included as a predictor in the second block with changes in fat gram and kilocalorie intakes. The adherence models for weight change were also built in a hierarchical fashion, with the design variables entered in the first block, followed by dietary adherence variables in the second block with the change in self-efficacy entered in the last block. This allowed us to determine the effect of self-efficacy change on weight change after controlling for changes in dietary adherence. Multicollinearity between dietary intake variables and also between dietary adherence variables necessitated the fitting of mixed models considering each intake and adherence variable separately as correlates of weight change. The Sobel test was used to explore the possible mediating effects of fat gram adherence and kilocalorie adherence on weight loss at each time point (Preacher and Hayes 2004); however, there were no significant mediation effects for dietary adherence at any time point.

Model assessment supported the statistical assumptions underlying linear mixed modeling yet revealed eight multivariate outliers, six in the two main self-efficacy models with change in kilocalorie and fat gram intake and two additional outliers in the two adherence models. These outliers were assessed via sensitivity analyses and were ultimately excluded from analyses because they overly influenced the results. This set of outliers comprised 4.5% of the total sample and had a higher mean weight loss at 18 months [22.59 (SD = 5.55)%],  $t(174) = -8.79$ ,  $p < 0.001$  with a marginally greater improvement in



self-efficacy [37.02 (SD = 41.12)%],  $t(174) = 1.87$ ,  $p = 0.06$ ) compared to the rest of the sample. With a mean age and total years of education similar to the rest of the sample, the outliers were from all four randomization groups, consisted of three men and five women and were mostly Caucasian ( $n = 7$ ) with one African-American. For kilocalorie adherence, the largest proportion these participants were “adherers” at 6 and 12 months and equally divided between “over consumer” and “adherers” at 18 months. The outliers were mainly “under consumers” at 6 months, “over consumers” or “under consumers” at 12 months, and “adherers” at 18 months with respect to their fat gram adherence.

## Results

Table 1 summarizes the baseline demographic characteristics of the sample by randomization group. No significant demographic differences were found between the groups. Table 2 shows that there were also no baseline differences in the independent or outcome variables, all  $p > 0.29$ . There were no group differences, i.e., randomization, diet, or preference, among the three adherence categories for fat gram adherence or kilocalorie adherence, all  $p > 0.11$ . Most participants were “adherers” at 6 and 12 months and

“over consumers” at 18 months for the kilocalorie goal while most were “over consumers” at all time points for the fat gram goal. See Table 3.

No significant differences between the diet groups were observed over time (i.e., no diet by time interactions) for weight, self-efficacy, kilocalorie, or fat gram change, but a significant preference by time interaction was observed for weight loss [ $F(2,167) = 4.49$ ,  $p = 0.01$ ] with a marginal preference by time interaction for a decrease in fat gram intake [ $F(2,167) = 2.34$ ,  $p = 0.09$ ]. A significant effect of preference on weight loss has been reported previously in the main outcome paper for the PREFER study (Burke et al. 2007b). Significant time effects (i.e., within group changes) were observed where fat gram intake decreased [ $F(2,167) = 11.35$ ,  $p < 0.001$ ] and self-efficacy increased [ $F(2,167) = 3.12$ ,  $p = 0.04$ ]. Table 2 shows the mean changes from baseline in weight, self-efficacy, kilocalorie and fat gram intake among the four randomization groups. Figure 2 illustrates the mean weights and WEL scores for the total sample at baseline, 6, 12, and 18 months with self-efficacy changes mirroring weight changes. As the greatest increase in self-efficacy occurred from baseline to 6 months [11.81 (SD = 28.83)],  $t(169) = 5.34$ ,  $p < 0.001$ , the greatest weight loss occurred [−6.61 kg (SD = 5.55)],  $t(169) = 15.54$ ,  $p < 0.001$ . Very little change occurred in self-efficacy during months 6–12

**Table 1** Baseline demographic characteristics by randomization groups

	Preference-Yes		Preference-No	
	STD-D ( $n = 47$ )	LOV-D ( $n = 33$ )	STD-D ( $n = 46$ )	LOV-D ( $n = 44$ )
Gender, $n$ (%) <sup>*</sup>				
Female	42 (89.4)	26 (78.8)	42 (91.3)	40 (90.9)
Male	5 (10.6)	7 (21.2)	4 (8.7)	4 (9.1)
Race, $n$ (%) <sup>**</sup>				
White	33 (70.2)	24 (72.7)	32 (69.6)	30 (68.3)
Non-white	14 (29.8)	9 (27.3)	14 (30.4)	14 (31.8)
Marital status, $n$ (%) <sup>**</sup>				
Never married	10 (21.7)	6 (18.8)	9 (19.6)	8 (18.2)
Married/living with partner	27 (58.7)	21 (65.6)	30 (65.2)	29 (65.9)
Divorced/separated	9 (19.6)	5 (15.6)	7 (15.2)	7 (15.9)
Employment, $n$ (%) <sup>*</sup>				
Full time	39 (83.0)	27 (81.8)	38 (82.6)	35 (79.5)
Part time	4 (8.5)	2 (6.1)	4 (8.7)	3 (6.8)
Other	4 (8.5)	2 (6.1)	4 (8.7)	6 (13.6)
Age (years), $M$ (SD) <sup>***</sup>	43.04 (9.46)	44.73 (8.51)	43.50 (8.72)	45.45 (8.59)
Education (years), $M$ (SD) <sup>***</sup>	15.09 (2.63)	14.88 (2.40)	15.30 (2.39)	15.30 (2.72)

Note: Data are missing on two participants for marital status and employment

<sup>\*</sup>Fisher’s exact test (gender,  $p = 0.36$ ; employment,  $p = 0.97$ )

<sup>\*\*</sup>Pearson-chi square (race,  $p = 0.97$ ; marital status,  $p = 0.99$ )

<sup>\*\*\*</sup>Kruskal–Wallis (age,  $p = 0.42$ ; education,  $p = 0.84$ )

**Table 2** Changes from baseline in body weight, self-efficacy, kilocalorie intake, and fat gram intake

	Preference-Yes				Preference-No				<i>p</i> -Values		
	STD-D ( <i>n</i> = 47)		LOV-D ( <i>n</i> = 33)		STD-D ( <i>n</i> = 46)		LOV-D ( <i>n</i> = 44)		Pref	Time	<i>P</i> × <i>T</i>
	<i>M</i>	SD	<i>M</i>	SD	<i>M</i>	SD	<i>M</i>	SD			
Weight, kg											
Baseline	96.6	12.6	98.3	11.8	93.5	16.6	94.9	16.7	.032	<0.001	0.012
6 months	90.5	12.8	91.2	13.5	86.8	17.9	88.1	17.4			
12 months	91.6	13.3	92.2	13.6	86.7	17.6	87.3	17.8			
18 months	93.6	13.7	95.1	12.9	88.2	17.4	89.2	17.4			
% change at 18 months	−3.0	5.2	−3.3	4.7	−5.7	6.1	−6.1	7.7			
Self-efficacy, (0–180 range)											
Baseline	105.9	31.8	105.2	36.1	106.7	32.7	117.3	34.0	.234	0.046	0.568
6 months	120.6	29.5	120.7	32.5	117.1	36.8	124.8	34.0			
12 months	117.4	29.5	116.9	36.7	117.9	36.0	124.4	35.4			
18 months	113.0	32.4	111.5	33.0	112.9	37.4	123.6	33.6			
% change at 18 months	12.6	39.2	15.3	45.5	8.0	30.6	11.9	40.7			
Kilocalories											
Baseline	1,940.5	627.5	2,124.6	801.7	2,117.3	659.0	1,973.1	605.6	0.111	0.053	0.450
6 months	1,480.7	621.1	1,619.2	641.0	1,568.5	569.2	1,401.9	317.5			
12 months	1,565.4	661.2	1,595.5	459.5	1,518.8	533.7	1,440.5	381.7			
18 months	1,578.6	637.1	1,669.6	535.5	1,542.3	520.7	1,478.7	362.1			
% change at 18 months	−15.9	28.5	−14.3	32.3	−22.6	29.0	−22.1	18.2			
Fat grams											
Baseline	75.7	31.5	83.3	36.9	86.5	35.0	77.2	30.2	0.134	<0.001	0.099
6 months	45.9	32.6	48.7	31.9	50.7	26.5	41.5	21.1			
12 months	52.4	37.1	51.7	25.1	50.3	26.3	45.1	21.7			
18 months	54.9	34.0	59.6	28.3	52.7	24.3	46.4	21.7			
% change at 18 months	−22.6	50.0	−16.7	52.7	−30.5	44.6	−35.6	26.6			

*Note:* No significant differences in baseline values between the randomization groups, *p*'s > 0.29. *P* × *T*: preference by time interaction. *p*-Values reflect changes over time from baseline to 18 months

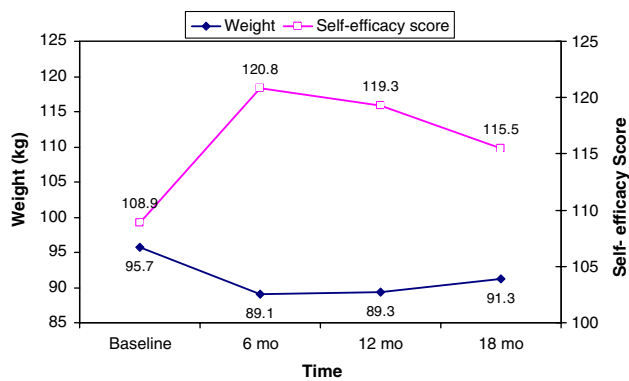
**Table 3** Kilocalorie and fat gram adherence categories over time (*N* = 170)

	6 months <i>n</i> (%)		12 months <i>n</i> (%)		18 months <i>n</i> (%)	
	Kilocalorie	Fat gram	Kilocalorie	Fat gram	Kilocalorie	Fat gram
Under consumers	38 (21.6)	56 (31.8)	34 (19.3)	41 (23.3)	33 (18.8)	32 (18.2)
Adherers	72 (40.9)	45 (25.6)	73 (41.5)	49 (27.8)	71 (40.3)	44 (25.0)
Over consumers	66 (37.5)	75 (42.6)	69 (39.2)	86 (48.9)	72 (40.9)	100 (56.8)

[−1.48 (SD = 24.02)], *t*(169) = 0.80, *p* = 0.42, and during this same time period weight loss plateaued [0.27 kg (SD = 2.84)], *t*(169) = −1.24, *p* = 0.21. In the 12- to 18-month maintenance phase, self-efficacy significantly decreased [−3.84 (SD = 24.83)], *t*(169) = 2.01, *p* = 0.04, and significant weight regain occurred [2.01 kg (SD = 3.21)], *t*(169) = −8.16, *p* < 0.001.

An examination of the main self-efficacy model, which included fat gram intake as an independent variable, revealed that the interaction of self-efficacy change and fat gram intake change was significantly associated with

weight loss over time, *F*(1,282) = 6.15, *p* = 0.01, indicating that the association of self-efficacy with weight loss varies by the level of fat gram intake. To clarify this relationship, we looked at the predicted percent weight loss based on percent change in fat gram intake and self-efficacy at one standard deviation above and below the mean for a participant in the Preference-Yes, LOV-D group at 18 months. We observed no association between self-efficacy change and weight change for those with a high level of change in fat intake (1SD above the mean) and a negative association between self-efficacy change and weight



**Fig. 2** Mean weights and self-efficacy scores over time collapsed across all groups

change for those who had a low level of change in fat intake (1SD below the mean). The preference by time interaction was significantly associated with percent weight loss in this model,  $F(2,168) = 4.11$ ,  $p = 0.02$ ; the Preference-No group lost [estimated mean (SE)] 2.23 (0.94)% more weight at 12 months,  $t(164) = -2.38$ ,  $p = 0.02$ , and 2.60 (0.93)% more weight at 18 months,  $t(173) = -2.79$ ,  $p = 0.006$ , than the Preference-Yes group. The finding that participants who were randomly assigned a diet without regard to preference lost more weight than those in the Preference-Yes group has been reported earlier by the authors (Burke et al. 2007b). The fat gram by time interaction was also associated with weight loss,  $F(2,211) = 3.15$ ,  $p = 0.04$ , where decreased fat gram intake over time was related to weight loss.

In the main self-efficacy model with kilocalorie intake as an independent variable, increase in self-efficacy was associated with weight loss,  $F(1,279) = 5.63$ ,  $p = 0.02$ . The preference by time interaction was significantly associated with weight loss  $F(2,168) = 4.65$ ,  $p = 0.01$ ; the Preference-No group again lost more weight than the Preference-Yes group as above. The interaction of decrease in kilocalorie intake and time was also highly significantly associated with weight loss in this model,  $F(2,209) = 7.22$ ,  $p = 0.009$ . There was no significant interaction between change in kilocalorie intake and change in self-efficacy,  $F(1,280) = 2.04$ ,  $p = 0.15$ .

The analyses of fat gram and kilocalorie adherence showed that in the first model with fat gram adherence as an independent variable, the main effect of fat gram adherence was significantly associated with weight loss [ $F(2,275) = 7.98$ ,  $p = 0.0004$ ] along with time [ $F(2,174) = 30.54$ ,  $p < 0.0001$ ]. When self-efficacy was added to the model with fat gram adherence, self-efficacy [ $F(1,311) = 15.17$ ,  $p = 0.0001$ ] and fat gram adherence [ $F(2,275) = 8.52$ ,  $p = 0.0003$ ] were both associated with weight loss.

No two-way interactions were significant. Over consumers lost [estimated mean (SE)] 1.59 (0.40)% less weight than the under consumers [ $t(293) = 3.95$ ,  $p < 0.0001$ ] and 0.83 (0.30)% less weight than the adherers [ $t(271) = 2.75$ ,  $p = 0.006$ ]. The estimated mean difference in weight loss [−0.76 (0.39)%] between the under consumers and adherers was only marginal [ $t(267) = -1.94$ ,  $p = 0.054$ ]. In the first model that included kilocalorie adherence as an independent variable, kilocalorie adherence was not associated with weight loss, [ $F(2,311) = 0.09$ ,  $p = 0.913$ ]. When self-efficacy and kilocalorie adherence were included in the model together, self-efficacy was significantly associated with weight loss [ $F(1,309) = 18.96$ ,  $p < 0.0001$ ], but adherence to the kilocalorie goal remained non-significant [ $F(2,307) = 0.27$ ,  $p = 0.762$ ].

We also examined the subscales of the WEL to determine if one particular domain of weight-loss specific self-efficacy was influencing the association of self-efficacy with weight loss. Certain scales had somewhat lower scores over time, e.g., availability compared to positive activities, suggesting that individuals were more confident in their ability to resist eating in enjoyable circumstances such as watching TV or reading, compared to when food was readily available on the weekends or at a party. See Table 4. We found that all five subscales, i.e., negative emotions, availability, social pressure, physical discomfort, and positive activities, were significantly associated with weight loss over time, all  $p$ 's  $< 0.006$ .

## Discussion

We examined self-efficacy related to changing eating behaviors in an 18-month behavioral intervention for weight loss to determine if changes in self-efficacy were associated with weight loss over time. Additionally, we investigated the role of dietary adherence by itself and together with self-efficacy to determine the impact on weight loss of adherence alone and in combination with self-efficacy. Our findings revealed that an increase in self-efficacy was associated with weight loss even after controlling for dietary adherence. Interestingly, we found that adherence to the fat gram goal and self-efficacy were associated with weight loss, but kilocalorie adherence was not. This might be explained by the difficulties associated with self-report data where the validity is sometimes questioned (Livingstone and Black 2003). For example, the “under consumer” adherence category may have been comprised of participants who were simply not recording all the food they ate, but this is difficult to discern from self-report data. Perhaps, fat gram adherence was better captured in the Three-Day Food Records than kilocalorie adherence because, with the messages portrayed in the lay

**Table 4** WEL subscales (range = 0–36): total sample mean scores over time ( $N = 170$ )

	Baseline		6 months		12 months		18 months	
	<i>M</i>	<i>SD</i>	<i>M</i>	<i>SD</i>	<i>M</i>	<i>SD</i>	<i>M</i>	<i>SD</i>
Negative emotions	19.0	9.9	21.5	9.5	20.9	10.1	20.1	10.0
Availability	17.0	8.6	20.2	8.5	20.0	8.8	19.2	9.1
Social pressure	22.9	8.4	25.4	8.0	25.6	8.1	24.5	8.2
Physical discomfort	25.4	7.6	27.3	7.4	26.8	7.6	26.5	7.5
Positive activities	24.9	7.3	27.4	6.6	28.8	5.9	26.5	6.9

media regarding reducing cholesterol and following a “heart-healthy” diet, participants were more sensitive to their fat gram goal and therefore more susceptible to social desirability. Additionally, reducing fat intake was emphasized in the study as a means to reduce blood cholesterol levels and to reduce caloric intake. Moreover, under reporting of energy intake is not uncommon (Martin et al. 1996; Mertz et al. 1991), especially in persons who have higher BMIs (Johansson et al. 2001). Few investigators have reported on the effect of self-reported dietary adherence on weight-loss outcomes; however, more successful weight loss has been associated with a higher level of adherence to the recording of foods consumed (Wadden et al. 2005; Burke et al. 2007a) and with sustained adherence to the assigned diet (Dansinger et al. 2005).

In order to remain true to the design of the parent study we examined the influence of the randomization variables, i.e., diet and preference, and found that preference for dietary treatment influenced weight loss but in an unanticipated way. Persons who were randomly assigned to the Preference-No group experienced greater weight losses than those who were assigned to receive their preferred diet. Similar findings regarding preference for treatment have been reported by other weight-loss researchers. Individuals who received weight maintenance guidelines differing from their preference experienced better weight maintenance than those who received their preferred guidelines (Vogels and Westerterp-Plantenga 2005), and participants who received group weight-loss therapy compared to individual therapy lost more weight even if individual therapy was their preference (Renjilian 2001).

This study provided us a unique opportunity to examine self-efficacy for eating behavior in a weight-loss study that compared two dietary approaches along with preference for treatment, in a weight-loss trial. We found no difference in changes in self-efficacy between the randomly assigned treatment groups. The groups received the same cognitive behavioral weight-loss intervention, e.g., goal setting, reinforcement strategies, and thus experienced similar weight losses and improvements in self-efficacy with

participants losing nearly 5% of their baseline weight at study completion. By the end of the trial, the overall improvement in self-efficacy was 11.7%, a finding that is consistent with others who noted that self-efficacy improved during the course of treatment (Clark et al. 1991; Ash et al. 2006; Burke et al. 2004). Other evidence supports the notion that improvement in weight-loss specific self-efficacy is a correlate of weight-loss success. A study of young adults in a 12-week weight reduction program that incorporated techniques to enhance self-efficacy found that as self-efficacy increased, food choices improved and weight loss increased (Roach et al. 2003). Others have noted that self-efficacy is associated with successful weight control both in individuals who are a healthy weight and those who had been overweight in the past (Kitsantas 2000). In an Australian population-based study, self-efficacy for preventing weight gain in the future was the variable most strongly associated with BMI, after controlling for confounding variables (Ball and Crawford 2006). In our study, despite self-efficacy significantly improving overall from baseline, it did decrease after the initial peak at 6 months. This finding is consistent with others who noted a reduction in eating and exercise self-efficacy during the course of the active intervention period (Linde et al. 2006). The challenge of continuing to maintain weight-loss behaviors could have become more apparent during the 18-month study than it was at baseline. During the first 6 months, participants experienced significant weight loss, which represents performance attainment, the most powerful source of self-efficacy enhancement. This likely explains the significant increase in self-efficacy at 6 months. However, with the decreasing frequency of group sessions and submitted diaries with feedback and reinforcement from the interventionists during the second 6 months of the study, participants began to gradually regain weight and experience decreasing self-efficacy.

Our investigation has several strengths including the examination of self-efficacy in the context of a long-term weight-loss study with a 6-month, no-contact maintenance phase, good retention of participants with 76% of individuals enrolled completing the study, and a 29.3%

minority representation. We explored the impact of the different subscales of the WEL on weight loss, which has not been previously examined to our knowledge, and found that the five domains of weight-loss specific self-efficacy were all associated with weight loss. Because the sample was recruited using multiple sources from a diverse population of community-dwelling individuals, these findings could be well generalized to both women and minorities. Only 12.1% of the participants were male; therefore, the generalizability of these findings to men may be limited. Other limitations include that the investigation was a secondary data analysis, the potential unreliability of the self-reported dietary data, and the questionable sensitivity of the WEL instrument for measuring weight-loss specific self-efficacy. Because the questions ask only about resisting eating foods in various situations, the instrument may not be considered comprehensive. 'Resisting' a poor food choice is only one part of the behavior change that must occur in order to promote weight loss. The WEL questionnaire does not assess one's ability to make positive food selections, such as choosing fruits and vegetables, which support weight loss and lifestyle modification. The focus of the cognitive behavioral weight-loss intervention was directed to positive eating behaviors, e.g., the available healthy food choices, rather than on the denial of foods. Thus, this instrument may lack thoroughness in assessing self-efficacy for weight loss, and future research should measure weight-loss specific self-efficacy more comprehensively. Moreover, a multi-factorial behavior, such as weight management, includes both healthy eating and regular physical activity, and requires multiple measures of self-efficacy (Bandura 1997). Therefore, it would be important to also measure self-efficacy for exercise.

Our findings indicate that self-efficacy improved significantly, adherence to the fat gram goal was associated with weight loss, and that weight loss was significant over time. These findings suggest that enhancement in weight-loss specific self-efficacy does support successful weight loss. This cognitive behavioral intervention included specific strategies that may have increased self-efficacy for weight loss, e.g., goal setting, verbal persuasion, feedback, and reinforcement of success. Future studies should examine the effect of interventions that further support adherence to the fat gram goal and are even more explicitly designed to increase weight-loss specific self-efficacy.

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## **APPENDIX B**

### **IRB APPROVAL**






# University of Pittsburgh

## *Institutional Review Board*

3500 Fifth Avenue  
Ground Level  
Pittsburgh, PA 15213  
(412) 383-1480  
(412) 383-1508 (fax)

### MEMORANDUM

TO: Melanie T. Warziski, BSN, RN

FROM: Sue R. Beers, PhD, Vice Chair 

DATE: September 27, 2007

SUBJECT: IRB #0509159: Weight Loss Maintenance: Exploring Racial Differences

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Your renewal of the above-referenced proposal has received expedited review and approval by the Institutional Review Board under 45 CFR 46.110 (4,7). **This approval is for analysis of data only.**

Approval Date: September 20, 2007

Renewal Date: September 28, 2008

The protocol and consent forms, along with a brief progress report must be resubmitted at least **one month prior** to the renewal date noted above as required by FWA00006790 (University of Pittsburgh), FWA00006735 (University of Pittsburgh Medical Center), FWA00006600 (Children's Hospital of Pittsburgh), FWA00003567 (Magee-Womens Health Corporation), FWA00003338 (University of Pittsburgh Medical Center Cancer Institute).

**Please be advised that your research study may be audited periodically by the University of Pittsburgh Research Conduct and Compliance Office.**

SRB:kh

## **APPENDIX C**

### **QUESTIONNAIRES/INSTRUMENTS**

Experiences Associated with Following a Low-fat Diet (ELF)

Barriers to Healthy Eating (BHE)

Weight Efficacy Lifestyle (WEL)

Self-Efficacy for Exercise Scale (SEE)

Behavioral Strategy Survey (BSS)

Paffenbarger Activity Questionnaire (PAQ)

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(For internal use only)

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## EXPERIENCES ASSOCIATED WITH FOLLOWING A LOW-FAT DIET

Center for Research in Chronic Disorders

ID Number:

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Administration Date:

--	--

(month)

--	--

(day)

--	--	--	--

(year)

( FOR STAFF USE ONLY )

Below we have listed some things which participants report are associated with following a low-fat diet. For each item, please indicate the extent to which this factor has made it difficult for you to follow your eating plan in THE PAST 6 MONTHS.

Since you began the weight loss eating plan in this study, do you . . .

	<i>Strongly Disagree</i>				<i>Strongly Agree</i>
	1	2	3	4	5
1. Feel you are reducing your risk of heart disease?	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
2. Feel you are reducing your risk of other diseases?	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
3. Feel you are reducing your risk of coronary heart disease?	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
4. Feel better about yourself?	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
5. Have more energy?	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
6. Feel your diet is setting a good example for your family?	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
7. Feel you are improving your general health?	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
8. Exercise more?	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
9. Feel physically uncomfortable after eating high-fat foods?	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
10. Dislike the taste of fat?	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>

Since you began the weight loss eating plan in this study, do you . . .

	<i>Strongly Disagree</i>				<i>Strongly Agree</i>
	1	2	3	4	5
11. Spend extra time shopping for food?	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
12. Spend extra time planning your meals?	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
13. Spend extra time preparing meals?	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
14. Spend extra money on food?	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
15. Limit your choice of restaurants?	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
16. Eat in restaurants less often?	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
17. Have difficulty maintaining a low-fat diet while traveling?	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
18. Have cravings for some of your favorite high-fat foods?	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
19. Find eating less satisfying?	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
20. Feel deprived when you cannot eat rich desserts?	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
21. Feel deprived if you eat a low-fat meal in a restaurant?	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
22. Find eating more satisfying?	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
23. Feel you are bothering your family sometimes?	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
24. Find that family members complain about the low-fat diet?	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
25. Sometimes prepare separate meals for yourself and other family members?	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
26. Find that your spouse/family discourages you from staying on a low-fat diet?	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>



3	3	6
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(For internal use only)

0	6	0
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## BARRIERS TO HEALTHY EATING

Center for Research in Chronic Disorders

ID Number:

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Administration Date:

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(month)

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(day)

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(year)

( FOR STAFF USE ONLY )

Below we have listed some things which participants report can make it difficult to change their eating habits. For each item, please indicate the extent to which this factor has made it difficult for you to follow appropriate eating habits in THE PAST 6 MONTHS.

	<i>Not at all a problem for me</i>				<i>A very important problem for me</i>
	1	2	3	4	5
1. Appropriate foods are not available in my home.	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
2. My family does not support my efforts to change my diet.	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
3. I have trouble estimating appropriate portion sizes.	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
4. It is difficult to motivate myself to eat appropriately.	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
5. I use food as a reward or treat for myself.	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
6. It is difficult to find time to plan appropriate meals for myself.	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
7. I don't see any benefits from my efforts to lose weight.	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
8. It is difficult to shop for one person in the grocery store.	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
9. I don't know what foods I should eat to lose weight.	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
10. I have difficulty controlling my eating when I am with friends.	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>



	<i>Not at all a problem for me</i>				<i>A very important problem for me</i>
	1	2	3	4	5
11. When I am very hungry I have trouble controlling what I eat.	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
12. Losing weight is rewarding but I have trouble staying motivated to keep off the weight I lost.	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
13. Changing my diet to reduce calories and fat seems too complicated.	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
14. I feel deprived when I have to restrict so many foods.	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
15. I find it difficult to select the appropriate foods when shopping.	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
16. I never feel that my appetite is satisfied when I am trying to lose weight.	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
17. The foods that are reduced in fat and calories cost more than I can afford.	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
18. The taste of low-fat / low-calorie foods is different.	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
19. Resisting tempting high fat / high calorie foods in my work setting is difficult.	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
20. When I am busy or feeling overwhelmed, I find it difficult to remember all the rules about what foods are appropriate.	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
21. When I am with my family I find it difficult to watch what I eat.	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
22. My friends do not support me when I try to change my eating.	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>



Instrument Number:

3	5	3
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(For internal use only)

Study ID:

0	5	4
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**WEL**

## Center for Research in Chronic Disorders

ID Number:

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Administration Date:

		/			/				
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(month)

(day)

(year)

Visit Number:

☐
☐
☐
☐

Baseline

6 months

12 months

18 months

( FOR STAFF USE ONLY )

Please use the following example to answer all questions:

Shade circles like this:



Not like this:



This form describes some typical eating situations. Everyone has situations which make it very hard for them to manage their weight. The following pages contain a number of situations relating to eating patterns and attitudes.

Please read each situation listed below and decide how confident (or certain) you are that you will be able to resist eating in each of the difficult situations. On a scale from 0 ("Not Confident") to 9 ("Very Confident") choose ONE number that reflects how confident you feel now about being able to successfully resist the desire to eat. Fill in the circle below the number that you have chosen for your answer.

***I am confident that . . . .******Not Confident  
At All******Very  
Confident***

0	1	2	3	4	5	6	7	8	9
---	---	---	---	---	---	---	---	---	---

- |  |                       |                       |                       |                       |                       |                       |                       |                       |                       |                       |
|--|-----------------------|-----------------------|-----------------------|-----------------------|-----------------------|-----------------------|-----------------------|-----------------------|-----------------------|-----------------------|
| 1. I can resist eating when I am anxious (or nervous).         | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> |
| 2. I can control my eating on the weekends.                    | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> |
| 3. I can resist eating even when I have to say "no" to others. | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> |
| 4. I can resist eating when I feel physically run down.        | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> |
| 5. I can resist eating when I am watching TV.                  | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> |

40433



***I am confident that . . . .***

	<div> <b>Not Confident</b>  <b>At All</b> </div> <div> <b>Very</b>  <b>Confident</b> </div>									
	0	1	2	3	4	5	6	7	8	9
6. I can resist eating when I am depressed (or down).	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
7. I can resist eating when there are many different kinds of food available.	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
8. I can resist eating even when I feel it's impolite to refuse a second helping.	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
9. I can resist eating even when I have a headache.	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
10. I can resist eating when I am reading.	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
11. I can resist eating when I am angry (or irritable).	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
12. I can resist eating even when I am at a party.	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
13. I can resist eating when others are pressuring me to eat.	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
14. I can resist eating when I am in pain.	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
15. I can resist eating just before going to bed.	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
16. I can resist eating when I have experienced failure.	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
17. I can resist eating even when high calorie foods are available.	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
18. I can resist eating even when I think others will be upset if I don't eat.	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
19. I can resist eating when I feel uncomfortable.	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
20. I can resist eating when I am happy.	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>



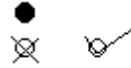


Instrument Number:

7 7 8

(For internal use only)

Shade circles like this: ●

Not like this: ⊗

Study ID:

1 1 3

## SELF-EFFICACY FOR EXERCISE SCALE

Center for Research in Chronic Disorders

ID Number:

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Administration Date:

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(month)

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(day)

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(year)

( FOR STAFF USE ONLY )

***How confident are you right now that you could exercise three times per week for 20 minutes if:***

	<u>Not Confident</u>										<u>Very Confident</u>	
	0	1	2	3	4	5	6	7	8	9	10	
1. the weather was bothering you?	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	
2. you were bored by the program or activity?	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	
3. you felt pain when exercising?	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	
4. you had to exercise alone?	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	
5. you did not enjoy it?	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	
6. you were too busy with other activities?	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	
7. you felt tired?	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	
8. you felt stressed?	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	
9. you felt depressed?	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	



Instrument Number:

7 7 9

(For internal use only)

Shade circles like this: ●

Not like this:

Study ID:

1 1 3

**BEHAVIORAL STRATEGY SURVEY**

Center for Research in Chronic Disorders

ID Number:

Administration Date:

(month)

(day)

(year)

( FOR STAFF USE ONLY )

This questionnaire is asking you about strategies you learned in the PREFER Study and if they have been useful in helping you maintain your weight loss. Please complete it to the best of your ability. For each question, please estimate on the scale provided what percent of the time in the last 18 months you used these strategies. For example, if you never did what is being asked -- you answer 0%. If you do it most of the time, select 80% or 90%.

	Percent ( % ) of the time										
	0	10	20	30	40	50	60	70	80	90	100
1. How often did you self-monitor your food intake including total calories and total fat grams?	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
2. How often did you self-monitor your physical activity including type of activity & total minutes?	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
3. How often did you increase your daily physical activity (take the stairs, park further away, walk instead of drive)?	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
4. How often did you include scheduled physical exercise in your day?	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
5. How often did you use portion control methods (weighing your food, using references of serving size, etc.) to control your food intake?	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
6. How often did you practice being assertive with others to meet your healthy lifestyle goals (for example, reminding others of your healthy eating plan or not giving in to pressure to eat)?	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>

(continued on next page)

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	<i>Percent ( % ) of the time</i>										
	0	10	20	30	40	50	60	70	80	90	100
7. How often did you read food labels while grocery shopping, looking at total calories, fat grams, and healthy claims ("reduced fat," "low-cal," "light," etc.)?	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
8. How often did you modify your recipes when making foods (reducing or substituting high-fat or high-calorie ingredients with healthier choices)?	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
9. How often did you handle cues (triggers) in your surroundings that may promote unhealthy choices (popcorn at the movies, snacking while watching television, high-calorie vending machines, etc.) and select a healthier choice?	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
10. How often did you use reminders in your surroundings for doing physical activity (keep tennis shoes in sight, set an alarm to remind you to be active, make an "activity date" with a friend)?	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
11. How often did you use problem-solving tips in situations where it is difficult to follow a healthy eating plan (for example, eating a healthy snack before a party, ordering from the light menu, packing a low-calorie lunch for work)?	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
12. How often did you change negative thoughts you were having (excuse-making, "all or nothing" thinking, pessimism) that could interfere with your eating and physical activity plan?	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
13. How often did you feel you had the support of family and friends for sticking to your healthy eating and physical activity lifestyle?	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
14. How often did you use weighing yourself on a regular basis to prevent weight gain?	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
15. How often did you use increasing physical activity to prevent weight gain?	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>



**16. Did you regain 2 or more pounds?**

- ☐ 1 Yes ----> a. How often did you use your "restart plan" to prevent further weight gain?  
☐ 2 No

Percent ( % ) of the time										
0	10	20	30	40	50	60	70	80	90	100
<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>

**17. Have you had a major stressful event (such as marriage, new job, divorce, death in family) in the last 18 months?**

- ☐ 1 Yes ----> a. Please describe: \_\_\_\_\_  
☐ 2 No

(for office use only)

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- b. How much did this stressful event affect your eating habits?

*Using the following scale of 0-10, where 0 means "No effect" and 10 means the "Most effect" it could have, fill in the circle that corresponds to your answer:*

No effect

Most effect

0	1	2	3	4	5	6	7	8	9	10
<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>

Percent ( % ) of the time											
	0	10	20	30	40	50	60	70	80	90	100
18. How often does stress influence how you eat?	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
19. How often did you use tricks to lower your stress level (deep breathing, journal writing, exercise, relaxing hobbies, time management, etc.)?	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>





3. How many flights of stairs do you climb up each day? 

--	--

 (flights/day)  
(Let 1 flight = 10 steps)

4. List any sports or recreation you have actively participated in during the past week. Please include only the time you were physically active (example: actual time in walking, swimming, gardening, etc.):

<u>Sport, Recreation, or Other Physical Activity</u>	<u>Number of times/week</u>	(Average time per episode)		(For office use only)								
		<u>Hours</u>	<u>Minutes</u>	(Total Minutes)	(Activity Code)							
a.) _____	_____	_____	_____	<table border="1" style="display: inline-table; width: 30px; height: 20px;"><tr><td></td><td></td></tr></table>			<table border="1" style="display: inline-table; width: 30px; height: 20px;"><tr><td></td><td></td></tr></table>			<table border="1" style="display: inline-table; width: 30px; height: 20px;"><tr><td></td><td></td></tr></table>		
b.) _____	_____	_____	_____	<table border="1" style="display: inline-table; width: 30px; height: 20px;"><tr><td></td><td></td></tr></table>			<table border="1" style="display: inline-table; width: 30px; height: 20px;"><tr><td></td><td></td></tr></table>			<table border="1" style="display: inline-table; width: 30px; height: 20px;"><tr><td></td><td></td></tr></table>		
c.) _____	_____	_____	_____	<table border="1" style="display: inline-table; width: 30px; height: 20px;"><tr><td></td><td></td></tr></table>			<table border="1" style="display: inline-table; width: 30px; height: 20px;"><tr><td></td><td></td></tr></table>			<table border="1" style="display: inline-table; width: 30px; height: 20px;"><tr><td></td><td></td></tr></table>		
d.) _____	_____	_____	_____	<table border="1" style="display: inline-table; width: 30px; height: 20px;"><tr><td></td><td></td></tr></table>			<table border="1" style="display: inline-table; width: 30px; height: 20px;"><tr><td></td><td></td></tr></table>			<table border="1" style="display: inline-table; width: 30px; height: 20px;"><tr><td></td><td></td></tr></table>		
e.) _____	_____	_____	_____	<table border="1" style="display: inline-table; width: 30px; height: 20px;"><tr><td></td><td></td></tr></table>			<table border="1" style="display: inline-table; width: 30px; height: 20px;"><tr><td></td><td></td></tr></table>			<table border="1" style="display: inline-table; width: 30px; height: 20px;"><tr><td></td><td></td></tr></table>		

5. Which of these statements best expresses your view? (Choose only one response.)

- ☐ 1 I exercise enough to keep healthy
- ☐ 2 I ought to exercise more
- ☐ 3 Don't know

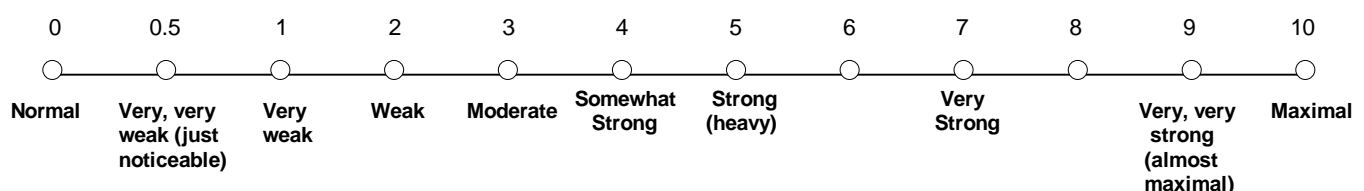
6. At least once a week, do you engage in regular activity akin to brisk walking, jogging, bicycling, swimming, etc., long enough to work up a sweat, get your heart pumping, or get out of breath?

- ☐ 1 Yes ----> List activity: \_\_\_\_\_ How many times per week? 

--	--
- ☐ 2 No -----> Why not: \_\_\_\_\_

(For office use only)				
(Activity Code)				
<table border="1" style="display: inline-table; width: 40px; height: 20px;"><tr><td></td><td></td></tr></table> . <table border="1" style="display: inline-table; width: 40px; height: 20px;"><tr><td></td><td></td></tr></table>				

7. When you are exercising in your usual fashion, how would you describe your level of exertion (degree of effort)? (Please fill in one circle only.)



8. On a usual weekday and a weekend day, how much time do you spend on the following activities? (Pick any weekday and record the number of hours you spend on **any** or **all** of the activity categories listed, "a" through "e," below. Write in the number of hours or minutes you spend on that activity category. Do the same for the weekend; pick either Saturday or Sunday and record the number of hours or minutes you spend on **any** or **all** of the activity categories. The number of total hours for each day should equal 24 hours.)

Usual  
WEEKDAY  
Hours/day

Usual  
WEEKEND  
Hours/day

- a.) **Vigorous activity** (digging in the garden, strenuous sports, jogging, aerobic dancing, brisk walking, sustained swimming, heavy carpentry, bicycling on hills, etc.)

(For office use only)  
(Total  
Minutes)

(Total  
Minutes)

(For office use only)  
(Activity Code)

 . 

- b.) **Moderate activity** (housework, light sports, regular walking, golf, yard work, lawn mowing, painting, repairing, light carpentry, ballroom dancing, bicycling on level ground, etc.)

(For office use only)  
(Total  
Minutes)

(Total  
Minutes)

(For office use only)  
(Activity Code)

 . 

- c.) **Light activity** (office work, driving car, strolling, personal care, standing with little motion, etc.)

(For office use only)  
(Total  
Minutes)

(Total  
Minutes)

(For office use only)  
(Activity Code)

 . 

- d.) **Sitting activity** (eating, reading, desk work, watching TV, listening to radio, etc.)

(For office use only)  
(Total  
Minutes)

(Total  
Minutes)

(For office use only)  
(Activity Code)

 . 

- e.) **Sleeping or reclining**

(For office use only)  
(Total  
Minutes)

(Total  
Minutes)

(For office use only)  
(Activity Code)

 .

## **APPENDIX D**

### **CONSENT FORM**





University of Pittsburgh

*School of Nursing*

University of Pittsburgh  
Institutional Review Board  
Current Approval Date: September 29, 2006  
Modification Approval Date: December 7, 2006  
Renewal Date: September 28, 2008  
IRB # 0509159

3500 Victoria Street  
Pittsburgh, Pennsylvania 15261  
Fax: 412-624-2401

**CONSENT TO ACT AS A SUBJECT IN A RESEARCH STUDY**

TITLE: Weight Loss Maintenance: Exploring Racial Differences

PRINCIPAL INVESTIGATOR: Melanie T. Warziski, RN, BSN  
Doctoral Student, Graduate Student Researcher  
415 Victoria Building, Pittsburgh, PA 15261  
Phone: (412) 624-2229

CO-INVESTIGATORS: Lora E. Burke, PhD, MPH, RN  
Associate Professor of Nursing and Epidemiology  
415 Victoria Building, Pittsburgh, PA 15261  
Phone: (412) 624- 2305

Linda J. Ewing, PhD, RN  
Assistant Professor of Psychiatry and Psychology  
Western Psychiatric Institute and Clinic  
3811 O'Hara St., Pittsburgh, PA 15213  
Phone: (412) 647-3089

Susan M. Sereika, PhD  
Associate Professor, Nursing, Biostatistics, &  
Epidemiology  
360 Victoria Building, Pittsburgh, PA 15261  
Phone: (412) 624-0977

Stephen B. Thomas, PhD  
Director, Center for Minority Health  
125 Parran Hall, Pittsburgh, PA 15261  
(412) 624-5665

SOURCE OF SUPPORT: National Institutes of Health, NIN

Subject's Initials \_\_\_\_\_

***What is informed consent?***

The information that follows describes the objective, procedures, risks, benefits, restrictions, and requirements of this research study. Your signature on this form indicates that the study has been explained to you, and that you agree to participate in the study. Informed consent is the process of reading, reviewing, and signing this form.

***Why is this research being done?***

People have difficulty keeping their weight off after they lose weight. The purpose of this study is to look at how people do with managing their weight 1.5 years after being in a weight loss study, and to find out if there are differences in weight management between minorities and non-minorities. In order to better understand the experiences that people have after a weight loss study, we are asking you to participate in this study. Your participation in this study will help to increase our understanding of the factors involved in weight management.

***Who is being asked to take part in this study?***

Individuals who completed the last assessment appointment of the PREFER study are being asked to participate in this study.

***What procedures will be performed for research purposes?***

If you agree to take part in this research study, you will be asked to come to the School of Nursing at the University of Pittsburgh only once at 1.5 years after you have finished the PREFER study. You will be asked to fill out some questionnaires that you completed during the PREFER study, 2 new questionnaires, and have your weight and body fat measured. If you are unable to come into Oakland, we can discuss alternative means to obtain your weight. Someone will also telephone you on 2 occasions to ask you to recall what foods you ate in the last 24 hours.

***What are the possible risks and discomforts of this study?***

The risks of participating in this study are very small. The primary risk from this study is the mental discomfort some people may feel when they reveal private information about themselves. Revealing of personal information may occur on questionnaire or when being weighed. To lessen this discomfort, the questionnaires being used are standard questionnaires that are commonly used in research and clinical practice and we will weigh you in a private room. No procedure with any risks is being conducted and no other possible physical or mental risks are anticipated. It is possible that the confidentiality of your information may be breached, but every possible effort will be made to protect your personal information. All information will be identified with an ID number only and will be stored in a locked file cabinet.

***What are the possible benefits from taking part in this study?***

There will be no specific benefit to you personally for taking part in this research study, but other people trying to maintain their weight loss may benefit from what we learn from this study.

***Will I be charged for any procedures performed as a part of this research study?***

You will not be billed for any research procedures that are a part of this study. A postage paid envelope will be provided to you to return all the questionnaires to the Principal Investigator.

Subject's Initials \_\_\_\_\_

***Who will pay if I am injured as a result of taking part in this study?***

Emergency medical treatment will be provided for injuries solely and directly related to your participation in this research study by the hospitals of the University of Pittsburgh Medical Center in the unlikely event that you are injured during this study. If you believe that you are injured as a result of the research procedures being performed, please immediately contact the Principal Investigator or one of the co-investigators listed on the first page of this form. You will not receive any monetary payment for, or related to, any injury you experience in relation to this study.

***Will I be paid if I take part in this study?***

You will receive a \$25 gift certificate to Giant Eagle grocery stores after completing the questionnaires, two 24-hour dietary recalls, and weight and body fat measurement.

***Will anyone know that I am taking part in this research study?***

Any information about you obtained from this study will be kept as confidential (private) as possible. All records related to your participation in this study will be stored in a locked file cabinet. You will be identified on these records by a study ID number rather than your name, and the information linking these ID numbers with your identity will be kept separate from the research records.

You will not be identified by name in any paper or publication of the research results unless you sign a separate form giving your permission (release). In a rare situation, your records may be released in response to an order from a court of law. If the researchers discover that that you or someone with whom you are involved is in serious danger or harm, they will need to inform the appropriate agencies as required by Pennsylvania law. Authorized persons from the study sponsor (National Institutes of Health, NINR) and/or the University Research Conduct and Compliance Office may possibly examine your research records.

Only the researchers listed on the first page of this form and their staff will be able to gain access to your records. All information about your involvement in this study- including answers to questionnaires- will be handled in a confidential way, consistent with other hospital medical records.

***How can I get more information about this research study?***

You may contact the Principal Investigator, Melanie Warziski, at (412) 624-2229. If you have any questions about your rights as a research participant, please contact the Human Subject Protection Advocate of the IRB office at 1-866-212-2668.

***Is my participation in this research study voluntary?***

Yes. Your participation in this study is completely voluntary. You may choose not to take part in this study or you may stop participating at any time during the study, even after you have signed this form. Whether or not you give your consent to participate in this study will have no impact on your current or future relationship with the University of Pittsburgh or the UPMC Health System.

Subject's Initials \_\_\_\_\_

***May I withdraw my consent for participation in this study at a future date?***

You may withdraw your consent for participation in this study at any time. To formally withdraw your consent to participate in this study, you should send a written and dated notification of this decision to the Principal Investigator of this study at the address listed on the first page of this form. Any identifiable research information recorded from your participation in this study before the date that you formally withdrew your consent may continue to be used by the investigators for the research purposes described above.

\*\*\*\*\*

**VOLUNTARY CONSENT**

I have read and reviewed the consent form for this research study. All of the above has been explained to me and all of my questions have been answered. I understand that I am encouraged to ask questions about any aspect of this research study during the course of this study, and that such future questions will be answered by the researchers listed on the first page of this form.

I understand that my participation in this study is voluntary and that I may refuse to participate or withdraw my consent and stop taking part in this study at any time.

Any questions that I have about my rights as a research participant will be answered by the Human Subjects Protection Advocate of the IRB Office, University of Pittsburgh (1-866-212- 2668).

By signing this form, I agree to participate in this research study. I will receive a copy of this consent form.

\_\_\_\_\_  
Participant's Signature

\_\_\_\_\_  
Date and Time

\_\_\_\_\_  
Printed Name of Participant

**CERTIFICATION OF INFORMED CONSENT**

I certify that I have explained the nature and purpose of this research study to the above-named individual, and I have discussed the potential benefits and possible risks of study participation. Any questions the individual has about this study have been answered, and we will always be available to answer any future questions.

\_\_\_\_\_  
Printed Name of Person Obtaining Consent

\_\_\_\_\_  
Role in Research Study

\_\_\_\_\_  
Signature of Person Obtaining Consent

\_\_\_\_\_  
Date and Time

Subject's Initials \_\_\_\_\_

## **APPENDIX E**

### **RECRUITMENT LETTER**



# University of Pittsburgh

## *School of Nursing*

3500 Victoria Street  
Pittsburgh, Pennsylvania 15261  
Fax: 412-624-2401

Dear XXXX,

We hope this letter finds you well and keeping warm during these winter months. We are writing to ask you to help Melanie Warziski, a doctoral student in the School of Nursing, complete her dissertation study. Melanie has worked on the PREFER study for over two years and is interested in learning how people manage their weight after they have completed a weight loss study, especially more about what works and does not work. Thus, it is important for Melanie to get information from *all* of you, whether you have kept off the weight or if you have gained the weight back.

For this small study, you will need to come to the School of Nursing one time to have your weight measured. If you are unable to come into Oakland, we can discuss alternative means of obtaining your weight. You will also need to complete 6 short questionnaires. The questionnaires will take you about 20 minutes to complete. You will **NOT** need to complete the Three-Day Food Diary. Instead, Melanie will call you twice and ask you what you ate in the past 24 hours. There is **NO** fasting and **NO** blood draw in this study.

To thank you for your time, we will give you a \$25 gift certificate to the Giant Eagle grocery store once you have completed the study. We will pay for your parking, or if you take the bus, we will give you a bus ticket.

If you are interested in participating and helping Melanie complete her study, please call Melanie at (412) 624-2229. She will review the enclosed consent form with you and you may return it in the envelope provided.

We sincerely appreciate you taking the time to consider this request.

Sincerely,

Lora E. Burke, PhD, MPH, FAAN  
Principal Investigator, PREFER Study

Melanie Warziski, BSN, RN  
Doctoral Student

## **APPENDIX F**

### **HUMAN SUBJECTS TRAINING MODULES**



# **University of Pittsburgh**

**This is to acknowledge that**

**Melanie T Warziski**

**Completed the RPF Module**

**Human Subjects Research**

**Date of Completion: 2003-11-10**

**CertificateID:14856-36174**

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# **University of Pittsburgh**

**This is to acknowledge that**

**Melanie T Warziski**

**Completed the RPF Module**

## **Privacy Requirements for Researchers under HIPAA**

**Date of Completion: 2003-11-19**

**CertificateID:14856-36177**

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# University of Pittsburgh

**This is to acknowledge that**

**Melanie T Warziski**

**Completed the RPF Module**

**Research Integrity**

**Date of Completion: 2003-12-07**

**CertificateID:14856-36828**

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# **University of Pittsburgh**

**This is to acknowledge that**

**Melanie T Warziski**

**Completed the RPF Module**

## **UPMC HIPAA Security Awareness Training for Staff**

**Date of Completion: 2005-03-17**

**CertificateID:14856-54546**

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